USER:	**MCINTOSH-LITTLE, KIMBERLY B (kml)**
FOLDER:	**K060415 - 216 pages (FOI:08001429)**
COMPANY:	**MEDTRONIC SOFAMOR DANEK (MEDTSOFADANEA)**
PRODUCT:	**INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT, SOLID-SPHERE, LUMBAR (NVR)**
SUMMARY:	**Product: MODIFICATION TO: SATELLITE SPINAL SYSTEM**
DATE REQUESTED:	**Wed Apr 01 24:00:00 2009**
DATE PRINTED:	**Tue Nov 17 11:21:40 2009**
Note:	**Releasable Version**

Table of Contents

K060415

SATELLITE™ SPINAL SYSTEM
510(k) Summary
February 2006

JAN - 5 2007

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Edward S. Chin**
Group Director, Clinical and Regulatory Affairs

II. **Proprietary Trade Name: SATELLITE™ Spinal System**

III. **Classification Name: Orthosis, Spinal Intervertebral Fusion, Solid Sphere**

IV. **Regulation Number: Preamendment Device**

V. **Product Code: NVR**

VI. **Product Description**

The SATELLITE™ Spinal System consists of spheres manufactured from either cobalt chrome or medical grade PEEK-OPTIMA LT1, which may be implanted from L3-S1 to provide temporary stabilization in order to help promote fusion.

VII **Indications**

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

VIII **Substantial Equivalence**

The purpose of this submission was to add PEEK-OPTIMA LT1 spheres with Tantalum markers to the system. Documentation was provided which demonstrated the subject SATELLITE™ Spinal System devices to be substantially equivalent to the cobalt chrome SATELLITE™ Spinal System devices previously cleared in K051320 (SE 09/09/05).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

JAN - 5 2007

Re: K060415/S1
Trade Name: SATELLITE® Spinal System
Regulatory Class: Unclassified
Product Code: NVR
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060415

Device Name: SATELLITE™ Spinal System

Indications for Use:

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Quenn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060415/c

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

JAN - 5 2007

Re: K060415/S1
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Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060415

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Quenn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060415/c

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

DRAFT

Re: K060415/S1
Trade Name: SATELLITE® Spinal System
Regulatory Class: Unclassified
Product Code: NVR
Dated: September 28, 2006
Received: September 29, 2006

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Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K060415

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Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Quenn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060415/c

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K060415/S1
Trade Name: SATELLITE® Spinal System
Regulatory Class: Unclassified
Product Code: NVR
Dated: September 28, 2006
Received: September 29, 2006

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Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HF240	Stevens	12/22/06						
HFZ410	Bunch	12/26/06						

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 01, 2006

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS, TN 38132
ATTN: RICHARD TREHARNE

510(k) Number: K060415
Device: MODIFICATION TO: SATELLITE SPINAL SYSTEM

Extended Until: 02-OCT-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Medtronic
SOFAMOR DANEK

Regulatory Affairs Department

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
www.medtronic.com

tel 901.396.3133
fax 901.346.9738
tel 800.876.3133

July 31, 2006

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

Re: SATELLITE™ Spinal System - K060415

Dear Document Control Clerk:

On April 27, 2006, we received a list of questions regarding the above referenced 510(k). During the course of mechanical testing we have determined that additional time will be required to complete the testing and to write the test report. Based upon the time constraints, we are requesting a further extension of 60 days.

Thank you for your cooperation in this matter. If you have any questions, please call me at (901) 396-3133.

Sincerely,

Lee Grant
Supervisor, Regulatory Affairs

K3
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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 08, 2006

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS, TN 38132
ATTN: RICHARD TREHARNE

510(k) Number: K060415
Device: MODIFICATION TO: SATELLITE SPINAL SYSTEM

Extended Until: 03-AUG-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Medtronic
SOFAMOR DANEK

Regulatory Affairs Department

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
www.medtronic.com

tel 901.396.3133
fax 901.346.9738
tel 800.876.3133

May 5, 2006

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

Re: SATELLITE™ Spinal System - K060415

Dear Document Control Clerk:

On April 27, 2006, we received a list of questions regarding the above referenced 510(k). The FDA issued the letter on April 5, 2006, however, the request was inadvertently sent to Cytori Therapeutics instead of Medtronic Sofamor Danek. We were informed of the questions by Cytori representatives on April 27, 2006. Based upon this time lapse, and on today's teleconference discussions regarding to additional testing, we are requesting a 90-day extension.

Thank you for your cooperation in this matter. If you have any questions, please call me at (901) 396-3133.

Sincerely,

Lee Grant
Supervisor, Regulatory Affairs

K-20

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek, Inc.
c/o Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

APR - 5

Re: K060415
Trade Name: SATELLITE Spinal System
Dated: February 16, 2006
Received: February 17, 2006

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following items:

1. You propose the addition of spheres manufactured from PEEK-OPTIMA LT1 to the Satellite Spinal System. This system has unique geometry as compared to other legally marketed fusion devices and you have not provided clinical information on the safety and effectiveness of this device as an adjunct to fusion. You have provided data from two bench tests, subsidence and push-out, which demonstrate that the PEEK Satellite Spinal System performs differently from the cobalt chrome predicate. The overall effect that this change in material could have on the performance of the Satellite Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited understanding of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the performance of the device. Therefore, please provide clinical data that demonstrates equivalence in terms of safety and effectiveness of the PEEK Satellite Spinal System for the indication sought. Please be advised that prior to initiating a clinical trial in the United States you must submit an investigational device exemption (IDE) application for review by the FDA.

2. You have provided results of subsidence testing and push-out testing of your worst case PEEK device. The PEEK device exhibited a higher subsidence load and a higher push-out load than the predicate cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that are associated with changing the device material from cobalt chrome to PEEK. The PEEK device could fail at low compression loads (static and fatigue) as compared to a legally marketed predicate device. In addition, the PEEK device could be subject to wear. Therefore, please:

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a. Provide results of static and dynamic compression testing of the worst case PEEK device. Please compare the results of these tests to a legally marketed predicate fusion device and provide a physiologic justification showing that the strength exhibited by the device in static compression and compression fatigue is adequate.

b. Provide results of wear testing on the worst case PEEK device. This test should mimic abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with the literature.

3. You state that the subject devices are manufactured from PEEK-OPTIMA LT1 and tantalum. However, you have not provided any specific information on the materials. Please provide the manufacturer of the materials and any standards to which the materials conform. Please identify a predicate device which utilizes these same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility or material properties of the device.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Jonathan Peck at (301) 594-2036, extension 122. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Medtronic Sofamor Danek, Inc.
c/o Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

APR - 5

Re: K060415
Trade Name: SATELLITE Spinal System
Dated: February 16, 2006
Received: February 17, 2006

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following items:

1. You propose the addition of spheres manufactured from PEEK-OPTIMA LT1 to the Satellite Spinal System. This system has unique geometry as compared to other legally marketed fusion devices and you have not provided clinical information on the safety and effectiveness of this device as an adjunct to fusion. You have provided data from two bench tests, subsidence and push-out, which demonstrate that the PEEK Satellite Spinal System performs differently from the cobalt chrome predicate. The overall effect that this change in material could have on the performance of the Satellite Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited understanding of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the performance of the device. Therefore, please provide clinical data that demonstrates equivalence in terms of safety and effectiveness of the PEEK Satellite Spinal System for the indication sought. Please be advised that prior to initiating a clinical trial in the United States you must submit an investigational device exemption (IDE) application for review by the FDA.

2. You have provided results of subsidence testing and push-out testing of your worst case PEEK device. The PEEK device exhibited a higher subsidence load and a higher push-out load than the predicate cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that are associated with changing the device material from cobalt chrome to PEEK. The PEEK device could fail at low compression loads (static and fatigue) as compared to a legally marketed predicate device. In addition, the PEEK device could be subject to wear. Therefore, please:

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a. Provide results of static and dynamic compression testing of the worst case PEEK device. Please compare the results of these tests to a legally marketed predicate fusion device and provide a physiologic justification showing that the strength exhibited by the device in static compression and compression fatigue is adequate.

b. Provide results of wear testing on the worst case PEEK device. This test should mimic abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with the literature.

3. You state that the subject devices are manufactured from PEEK-OPTIMA LT1 and tantalum. However, you have not provided any specific information on the materials. Please provide the manufacturer of the materials and any standards to which the materials conform. Please identify a predicate device which utilizes these same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility or material properties of the device.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Jonathan Peck at (301) 594-2036, extension 122. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

MNM

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Peck	4/4/06						
Z40	Stevens	4/5/06						

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.
f/t:JHP:tlm:4-3-06

FILE COPY

OFFICE	SURNAME	DATE		OFFICE	SURNAME	DATE		OFFICE	SURNAME	DATE
Fis	fox	4/3/06								

U.S. GPO 1986-169-089

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 17, 2006

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS, TN 38132
ATTN: RICHARD TREHARNE

510(k) Number: K060415
Received: 17-FEB-2006
Product: MODIFICATION TO: SATELLITE SPINAL SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation

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K060415

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6024027-956733** Write the Payment Identification number on your check.

mpleted Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken perly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS TN 38132
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
621483635

2. CONTACT NAME
Richard Treharne

2.1 E-MAIL ADDRESS
rick.treharne@medtronic.com

2.2 TELEPHONE NUMBER (include Area code)
901-344-1124

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
901-346-9738

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
ologics License Application (BLA)
remarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

$3,833.00

23-Dec-2005

Form FDA 8601 (08/2003)

se Window

Print Cover sheet

3p
121 165

Medtronic

MEDTRONIC
SOFAMOR DANEK USA, INC.
1800 PYRAMID PLACE
MEMPHIS, TN 38132

WELLS FARGO BANK OHIO, N.A.
VAN WERT, OH

56-382
412

NO. 221353

Check Date	Check #
09/27/05	00221353

AMOUNT
$*****3,833.00

PAY
THREE THOUSAND EIGHT HUNDRED THIRTY THREE AND 00/100**********

TO THE ORDER OF
FOOD & DRUG ADMINISTRATION
PO BOX 956733
ST. LOUIS MO 63195-6733

273746

VOID AFTER 90 DAYS

Payment ID: MDL6024027-956733

[redacted] (b) (4)

AMOUNTS IN EXCESS OF $10,000 REQUIRE TWO SIGNATURES

CDRH SUBMISSION COVER SHEET

Date of Submission: 2-16-06 **FDA Document Number:**

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: Traditional X Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name: Medtronic Sofamor Danek		Establishment registration number: 1030489	
Division Name (if applicable):		Phone number (include area code): (901) 396-3133	
Street Address: 1800 Pyramid Place		Fax number (include area code): (901) 346-9738	
City: Memphis	State/Province: TN	Zip code: 38132	Country: USA
Contact Name: Richard Treharne			
Contact Title: Sr. Vice President Regulatory Affairs		Contact e-mail address: rtreharne@sofamordanek.com	

Section C — Submission Correspondent (if different from above)

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

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Section D1 — Reason for Submission – PMA,PDP, or HDE

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

New Device
☐ Additional or expanded indications
Other reason (specify):

☐ Change in technology
☐ Change in design

X Change in materials
☐ Change in manufacturing process

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Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data:
	2	3	4	X 510(k) summary attached
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 Exempt	1 Harmon Spinal Spheres (Pre-enactment Device)	1 Austenal Company, Surgical Products
2 K051320	2 SATELLITE Spinal System	2 Medtronic Sofamor Danek
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name:
Spinal Interlaminal Fixation Orthosis

Trade or proprietary or model name	Model Number
1 SATELLITE™ Spinal System	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

K041045	2 K051320	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: NVR	C.F.R. Section Pre-amendment Device	Device Class: Class I Class II X ☐ Class III ☐ Unclassified
Classification Panel: General, Restorative and Neurological Device		
Indications (from labeling): Please see attached indications sheet		

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

☐ Original ☐ Add ☐ Delete	FDA establishment registration number: 1824199	X Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number: 1824199
Division name (if applicable): Medtronic Sofamor Danek MFG (aka Warsaw MFG)		Phone number (include area code): 219-267-6826
Street address:		FAX number (include area code):

City Warsaw	State/Province: IN	Zip code: 46582	Country US

Contact name:

Contact title: Contact e-mail address:

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	X Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution Name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City:	State/Province:	Zip code:	Country:

Contact name:

Contact title: Contact e-mail address:

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City:	State/Province:	Zip code:	Country:

Contact name:

Contact title: Contact e-mail address:

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SATELLITE® Spinal System
510(k) Application
Table of Contents

CONFIDENTIAL

February 16, 2006

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

Re:	**Special 510(k):**	**Device Modification**
	Medical Specialty:	**General and Restorative and Neurological Device**
	Legally Marketed Device:	**SATELLITE® Spinal System (K051320)**

Dear Document Control Clerk:

This letter and two copies are being submitted as a **Special 510(k)** to modify a previously cleared SATELLITE® Spinal System (K051320, SE 09/09/05). The purpose of this 510(k) is to modify the device by changing the material from cobalt chrome to medical grade PEEK-OPTIMA LT1. From a regulatory point of view, we regard the subject SATELLITE® device to be substantially equivalent to the predicate SATELLITE® device. This application is being submitted in accordance with the CDRH's final guidance on the "New 510(k) Paradigm; Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."

We believe the products described in this submission are insignificant changes in design to similar types of categories of products previously cleared by the agency for Medtronic Sofamor Danek or its predecessors. The intended use and materials used to make the products have previously been cleared by the agency. From a regulatory point of view, we believe the subject components are substantially equivalent[1] to the aforementioned "legally marketed" and/or pre-amendment spinal fixation devices, including the previously cleared SATELLITE® Spinal

[1] The term "substantially equivalent" is used here as required and defined under the Federal Food, Drug, and Cosmetic Act and refers to the function and result of the predicate devices. Such a claim or final determination of "substantial equivalence" is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters, if any issues exist or arise in the future. (See *Federal Register*, Vol. 42, No. 163, Aug. 23, 1977, page 42525 and 42529.)

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System. We are submitting this pre-market notification for non-regulatory business reasons or in case the agency disagrees with our position.

Background Information

As previously stated, the FDA cleared a cobalt chrome version of the SATELLITE® Spinal System in K051320. At the time of the original filing, agency representatives stated that the initial application would be limited to devices manufactured from cobalt chrome, the material used to produce the pre-enactment Harmon Sphere device. However, the agency stated that once clearance was obtained subsequent submissions could be filed in order to change certain aspects of the device, including the material.

Historically, modifying pre-amendment devices that have subsequently been cleared through the 510(k) process is a recognized and accepted practice. Examples of such practices can be found within the Medtronic Sofamor Danek 510(k) files.

On March 20, 1998 the FDA declared the TOWNLEY® Pedicle Screw Plating System (K970599) to be substantially to a pre-amendment device. The original TOWNLEY® devices were manufactured from medical grade stainless steel. Eight months later the FDA granted Medtronic Sofamor Danek clearance of a titanium version of the product in K983706 (SE 11/12/98). Therefore, the agency has indeed established a precedent of allowing material changes to pre-amendment devices.

It should be noted that the TOWNLEY® Pedicle Screw Plating System received clearances for much broader pedicle screw indications, than the subject device. Included in the TOWNLEY® device clearance is the indication for degenerative disc disease, which is considered by the agency to be a Class III indication. The indications for the subject device are much more narrow and do not fall into the Class III category.

The FDA has granted clearances to six 510(k) applications seeking modifications to the original TOWNLEY® Pedicle Screw Plating Systems other than the aforementioned material change. These modifications have included the addition of cannulated screws, cortical bone screws, plates, and modified plate rings. Given the extensive nature of these changes, it is evident that the agency has established a precedent of allowing modifications to pre-amendment devices once they have obtained an initial 510(k) clearance. In the case of this submission, we are not seeking

any design changes with the exception of offering the device in an alternative material; a material that is commonly used in the manufacturing of spinal devices.

We have conducted a risk analysis and through the necessary verification and validation activities have determined that the design outputs of the modified device meet the design input requirements. In **Attachment 1** we provide a Summary of Design Control Activities meeting the "Special 510(k) Device Modification" requirements. The proposed modifications do not affect the device's intended use or alter the device's fundamental scientific technology.

(a) Device Name

Common or Usual Name: Solid Sphere
Proposed Proprietary or Trade Name: SATELLITE® Spinal System

(b) Manufacturing Facility

Medtronic Sofamor Danek Deggendorf
WerfstraBe 17
Deggendorf, GmBh
Warsaw Orthopedic, Inc. (also known as)
Medtronic Sofamor Danek Manufacturing, Inc.
2500 Silveus Crossing
Warsaw, Indiana 46582
Telephone: 219-267-6801

(c) Establishment Registration Number

1030489 Medtronic Sofamor Danek Inc., USA
3003006544 Medtronic Sofamor Danek Deggendorf, GmBh
1824199 Warsaw Orthopedic, also known as Medtronic Sofamor Danek Manufacturing, Inc. (For reference only)

(d) Classification

Regulatory Class:	Unclassified
Product Code:	NVR
Regulation Number:	Pre-amendment

(e) Performance Standards

We are unaware of any performance standards for this product presently.

(f) Labeling

A sample label is provided in **Attachment 2**. A draft package insert is provided in **Attachment 3**. This labeling is identical to that provided in the previously cleared

submission K051320. The electronic labeling provision (Section 206) in the recently enacted MDUFMA law (Medical Device User Fee and Modernization Act of 2002) says: *Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following: `Required labeling for prescription devices intended for use in health care facilities may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law and, that the manufacturer affords health care facilities the opportunity to request the labeling in paper form, and after such request, promptly provides the health care facility the requested information without additional cost.'.* Therefore, MSD reserves the right at a later date not to include a hard copy of a package insert such as shown in **Attachment 3** with every component described in this 510(k), but rather to instead include multiple language versions of sentences similar to: 'For the latest important medical information about this system including indications, contraindications, warnings, and precautions, use the internet to see an electronic version of this labeling information by going to www.xxxxxxxxxxx If a copy of this labeling is needed in paper form, please contact the company at _____ or call _____ and a hard copy will be provided promptly without additional cost'."

(g) Similarities and Differences

The subject SATELLITE® device is identical to the predicate SATELLITE® device with the exception of the material used to manufacture the device. **Table 1** summarizes these similarities and differences.

Table 1. Summary Comparison of Subject to Predicate Device

	Predicate SATELLITE® device	Subject SATELLITE® device
Intended Use/Indications for use	To help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal.	**Identical**
Implant Size Range	9.5mm – 19mm	Inclusive – 10mm – 16mm
Levels of attachment	L3-S1	**Identical**
Surgical technique	Anterior Approach	**Identical**
Material	Cobalt Chrome	PEEK-OPTIMA LT1/ Tantalum
Sterilization Method	Gamma	**Identical**
Fundamental Scientific Tech.	Spherical implant inserted into the disc space.	**Identical**

(h) Safety and Effectiveness

The modifications to the subject SATELLITE® implants included in this submission are minor and do not affect the safety or effectiveness of the SATELLITE® Spinal System.

Mechanical testing (subsidence and push-out) referenced in the Risk Analysis (**Attachment 1**) has demonstrated that the subject device outperformed the predicate SATELLITE® device in both test methods. The results are summarized in **Table 2**, while the complete test report is provided in **Attachment 1** of this submission. It should be noted that side-by-side testing was performed on the 10mm SATELLITE® spheres, although a smaller (9.5mm) cobalt chrome implant was previously cleared. At this time the smallest PEEK size we wish to obtain clearance for is the 10mm sphere, therefore, we considered it appropriate to compare identical sizes.

Table 2. Test Result Comparison of Subject to Predicate Device

Test Performed (10mm implants in all testing)	Predicate SATELLITE® Cobalt Chrome device	Subject SATELLITE® PEEK device
Subsidence Results	718N	**756N**
Push-out Results	49N	**57N**

(i) 510(k) Summary

A 510(k) summary for FDA distribution upon request is provided in **Attachment 4**.

(j) Substantial Equivalence

The documentation provided within this application demonstrates that the subject PEEK SATELLITE® device is substantially equivalent to cobalt chrome implants previously cleared in the SATELLITE® Spinal System 510(k) application.

(k) Truthful and Accurate Statement

A Truthful and Accurate Statement is attached to the end of this cover letter.

(l) Product Numbers/Engineering Drawings

A complete implant list is provided in **Attachment 5** of this submission. The subject devices appear in **bold** text, while the previously cleared devices appear in regular text. The instruments used with this device are general manual surgical instruments and are therefore considered to be Class I exempt. However, for the sake of completeness a listing of the instruments is also provided in **Attachment 5**. Drawings of all subject devices are provided in **Attachment 6** of this submission.

Indications Statement

In compliance with the form required after January 1, 1996, **Attachment 7** contains the indications for this device.

Confidentiality of Information

The enclosed materials and descriptions contain information that is trade secret or confidential under 21 CFR 20.61 and not disclosable to the public under the Freedom of Information Act (FOIA). If you are not able to assure us that the enclosed information will not be disclosed to the public, we request that this submission be handled by FDA in accordance with 21 CFR 20.44 relating to presubmission reviews. Consequently, until you hear otherwise from us, we ask that you keep our application for this device confidential. We consider this premarket notification confidential commercial information. If we disclose this application to anyone except consultants or employees, we will notify FDA.

If you have any questions regarding this submission, please call Lee Grant or me at (901) 396-3133. You may also email questions to Lee Grant at lgrant@sofamordanek.com or to me at rtreharne@sofamordanek.com. Notification of clearance of this 510(k), or requests for further information may be sent to Medtronic Sofamor Danek by fax to me at (901) 346-9738.

Sincerely,

Richard W. Treharne

Richard W. Treharne,
Sr. Vice President, Regulatory Affairs
Attachments

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Medtronic

SOFAMOR DANEK

Regulatory Affairs Department

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
www.medtronic.com

tel 901.396.3133
fax 901.346.9738
tel 800.876.3133

Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Vice President of Regulatory Affairs, at Medtronic Sofamor Danek, I believe to the best of my knowledge, all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.

Richard W. Treharne 16 Feb 06

Richard W. Treharne, Ph.D. Date
Senior Vice President Regulatory Affairs

---

*(Premarket Notification [510(k)] Number

*For a new submission, leave the 510(k) number blank.

K060307

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Attachment 1

Declaration of Conformity with Design Controls

Summary of Design Control Activities for the modified components of the SATELLITE® Spinal System

In this summary, we provide appropriate supporting data of design control activities within the meaning of §807.87(g). This summary includes the following:

- An identification of the Risk Analysis methods used to assess the impact of the modification on the device and its components as well as the results of the analysis:

  A Failure Mode and Effects Analysis was performed to identify possible hazards associated with the modified features of the SATELLITE® Spinal System. A summary of this analysis is included in this Summary of Design Control Activities.

- An identification, based on the Risk Analysis, of the verification and/or validation activities performed, including methods or tests used and the acceptance criteria applied.

  Based on the possible hazards identified in the Failure Mode and Effects Analysis, design verification was performed. A summary of this Design Verification is included in this Summary of Design Control and identifies the particular methods of verification used. These verification activities demonstrate that the possible risks identified are acceptable for the failure mode.

- A declaration of conformity with design controls

  The Declaration of Conformity is provided in this Summary of Design Control.

CONFIDENTIAL

Declaration of Conformity with Design Controls

Design Validation

As required by risk analysis, all verification and validation activities for this submission were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. Additional testing above and beyond the required verification / validation activities included to establish equivalence to the predicate device may be performed in the future for internal purposes.

FEB 8, 2006

Frank Bono — Date

Vice President, Development

Manufacturing Facility

The Medtronic Sofamor Danek manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30, and the records are available for review.

2/16/06

Tom Slagle — Date

Sr. Manager, Quality Engineering

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Change	Risk	Verification	Acceptance Criteria	Results of Verification
Change in material from cobalt chrome to PEEK	Material change could negatively impact subsidence or push-out.	Subsidence test and Push-out test of 10mm PEEK (worst case) and 10mm Cobalt Chrome (worst case).	Subsidence and Push –out Tests must demonstrate PEEK device to be substantially equivalent to predicate SATELLITE® device.	Testing (see report TR-06-329) demonstrated that PEEK was greater in [redacted (b) (4)] resistance than predicate SATELLITE device.

Randy Allard
Group Director of Development
Medtronic Sofamor Danek

February 8, 2006
Date

Medtronic
SOFAMOR DANEK

Design Verification Test Report

TR06-329

(b) (4)

Subsidence and Push-out Testing of 10 mm CoCr and PEEK Satellite Implants

Testing Performed by (b) (4)

(b) (4)

Prepared By:

Reviewed By:

Approved By:

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Attachment 2

Sample Label

Medtronic
SOFAMOR DANEK

10mm SATELLITE SPHERE
SIZE: 10mm
REF [Ref.-no.]
LOT 1234567www
Use by 2099-12-31 STERILE R

Medtronic
SOFAMOR DANEK

10mm SATELLITE SPHERE
SIZE: 10mm
REF [Ref.-no.]
LOT 1234567www
Use by 2099-12-31 STERILE R

Medtronic
SOFAMOR DANEK

10mm SATELLITE SPHERE
SIZE: 10mm
REF [Ref.-no.]
LOT 1234567www
Use by 2099-12-31 STERILE R

Medtronic
SOFAMOR DANEK

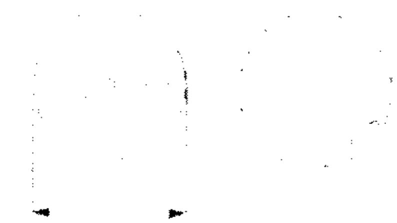
10mm SATELLITE SPHERE
SIZE: 10mm
REF [Ref.-no.]
LOT 1234567www
Use by 2099-12-31 STERILE R

Medtronic

10mm SATELLITE SPHERE
SIZE: 10mm
REF [Ref.-no.]
LOT 1234567www
Use by 2099-12-31 STERILE R

Made in Germany

Medtronic
SOFAMOR DANEK



MAT'L:
PEEK-OPTIMA®
OPTIMA

10mm SATELLITE SPHERE
SIZE: 10mm
QTY: 1

STERILE R

REF [Ref.-no.] LOT 1234567www Use by 2099-12-31

UCC: (01)00000000000000 (17)991231 (10)1234567www

The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established

!USA Rx only

Sterility assured only when package is undamaged.

Manufactured in:
Medtronic Sofamor Danek
Deggendorf GmbH
Werftstr. 17
94469 Deggendorf, Germany

Medtronic Sofamor Danek Inc.
1800 Pyramid Place
Memphis, TN 38132, USA
Telephone 800 933 2635
901 396 3133

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REF [Ref.-no.]
LOT 1234567ww
UCC (01)00000000000000 (17)991231 (10)1234567www
10mm SATELLITE SPHERE
SIZE: 10mm

Attachment 3

Draft Package Insert

SATELLITE® Spinal System

PRODUCT DESCRIPTION:

The SATELLITE® Spinal System is a spherical implant designed to hold bone parts in alignment while they heal in order to promote interbody fusion. These spheres may be placed between to vertebral bodies into the disc space. This system is limited to L3-S1. The device is fabricated from cobalt chrome. Alternatively, the device may be manufactured from PEEK-OPTIMA LT1 with TANTALUM markers. The system may be supplied sterile or non-sterile. The SATELLITE® implants are single-use implants and should never be reused under any circumstances. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog and/or or pricelist for further information about warranties and limitations of liability. Only a physician who is thoroughly familiar with the surgical aspects involved in this procedure, as well as its mechanical and material applications and limitations should use the product.

Indications for Use: The SATELLITE® Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE® Spinal System is intended to be used with bone graft.

CONTRAINDICATIONS: Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise)
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.

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11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.

12. Any case that requires the mixing of metals from two different components or systems.

13. Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or quality.

14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

15. Any patient unwilling to follow postoperative instructions.

POSSIBLE ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Loosening of the device.
2. Breakage of the device.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from the device in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function, (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysaesthesias, hyperaesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone.

13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stress shielding.
18. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
19. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
20. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
21. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia etc.
22. Change in mental status.
23. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNINGS: A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. It should be known that in some cases, use of this implant might not result in fusion. Further, the proper selection and compliance of the patient will greatly affect the results. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE FOR USE IN MOTION SPARING, NON-FUSION PROCEDURES HAS NOT BEEN ESTABLISHED.

Implant Selection: The selection of the proper size of the implant for each patient is crucial to the success of the procedure. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.

2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

3. Care should be used in the handling and storage of the implant component. Implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

4. The surgeon should be familiar with the various components before using the equipment and should personally verify that all parts and necessary instruments are present before the surgery begins. The SATELLITE® Spinal System components are not to be combined with the components from another manufacturer. Different metal types should never be used together.

5. Unless sterile packaged all parts and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Any instruction manuals should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

POSTOPERATIVE:

1. Detailed instructions on the use and limitations of the device for the selected indications should be given to the patient.

2. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the SATELLITE® Spinal System components should never be reused under any circumstances.

PACKAGING: Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic Sofamor Danek.

CLEANING AND DECONTAMINATION: Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION: Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted SATELLITE™ Spinal System component(s) ever "malfunctions". (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

If further directions for use of this system are needed, please check with MEDTRONIC SOFAMOR DANEK Customer Service. If further information is needed or required, please contact:

IN THE USA
Customer Service Division Tele: 800-876-3133
Medtronic Sofamor Danek or 901-396-3133
1800 Pyramid Place Telefax: 901-396-0356
Memphis, TN 38132 USA or 901-332-3920

IN EUROPE
Medtronic B.V.
Earl Bakkenstraat 10
6422 P J Herleen
The Netherlands
Tel: + 31 45 566 80 00

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CONFIDENTIAL

Attachment 4

510(k) Summary

SATELLITE™ SPINAL SYSTEM
510(k) Summary
February 2006

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Edward S. Chin**
Group Director, Clinical and Regulatory Affairs

II. **Proprietary Trade Name: SATELLITE™ Spinal System**

III. **Classification Name: Orthosis, Spinal Intervertebral Fusion, Solid Sphere**

IV. **Regulation Number: Preamendment Device**

V. **Product Code: NVR**

VI. **Product Description**

The SATELLITE™ Spinal System consists of spheres manufactured from either cobalt chrome or medical grade PEEK-OPTIMA LT1, which may be implanted from L3-S1 to provide temporary stabilization in order to help promote fusion.

VII **Indications**

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

VIII **Substantial Equivalence**

The purpose of this submission was to add PEEK-OPTIMA LT1 spheres with Tantalum markers to the system. Documentation was provided which demonstrated the subject SATELLITE™ Spinal System devices to be substantially equivalent to the cobalt chrome SATELLITE™ Spinal System devices previously cleared in K051320 (SE 09/09/05).

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Attachment 5

Implant and Instrument List

SATELLITE® Spinal System Implants

Implant Description	Reference Number	Levels of Attachment[1]	510(k) NUMBER
PEEK Implants			
SATELLITE® Spinal Implant 10mm diameter	**9000210**	**L/S**	**New**
SATELLITE® Spinal Implant 11mm diameter	**9000211**	**L/S**	**New**
SATELLITE® Spinal Implant 12mm diameter	**9000212**	**L/S**	**New**
SATELLITE® Spinal Implant 13mm diameter	**9000213**	**L/S**	**New**
SATELLITE® Spinal Implant 14mm diameter	**9000214**	**L/S**	**New**
SATELLITE® Spinal Implant 15mm diameter	**9000215**	**L/S**	**New**
SATELLITE® Spinal Implant 16mm diameter	**9000216**	**L/S**	**New**
Cobalt Chrome Implants			
SATELLITE® Spinal Implant 9.5mm diameter	8000209	L/S	K051320
SATELLITE® Spinal Implant 10mm diameter	8000210	L/S	K051320
SATELLITE® Spinal Implant 11mm diameter	8000211	L/S	K051320
SATELLITE® Spinal Implant 12mm diameter	8000212	L/S	K051320
SATELLITE® Spinal Implant 13mm diameter	8000213	L/S	K051320
SATELLITE® Spinal Implant 14mm diameter	8000214	L/S	K051320
SATELLITE® Spinal Implant 15mm diameter	8000215	L/S	K051320
SATELLITE® Spinal Implant 16mm diameter	8000216	L/S	K051320
SATELLITE® Spinal Implant 17mm diameter	8000217	L/S	K051320
SATELLITE® Spinal Implant 18mm diameter	8000218	L/S	K051320
SATELLITE® Spinal Implant 19mm diameter	8000219	L/S	K051320

For marketing or other reasons Medtronic Sofamor Danek reserves the right to change the tradename of any or all of the listed components. For example, the company may decide to make the SATELLITE® Spinal System its flagship system and discontinue or lose any individual system identity yet keep the components identified in this table as part of the SATELLITE® Spinal System. If that occurs, the affected components would begin receiving the SATELLITE® Spinal System package insert and the SATELLITE® trade name in replacement of its existing system name and insert. All other company labeling would be appropriately modified."

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[1]L= Lumbar, S = Sacrum

Attachment 6

Engineering Drawings

(b) (4)

Attachment 7

Indications of Use Statement

510(k) Number (if known): _____

Device Name: SATELLITE™ Spinal System

Indications for Use:

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Jonatha Peck

Subject: 510(k) Number K061415/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices. YES
- ☒ ~~NOT substantially equivalent to marketed devices~~.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☒ YES	☐ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

- ☒ A 510(k) summary OR ☐ A 510(k) statement
- ☒ The required certification and summary for class III devices
- ☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: NVR Class II

Additional Product Code(s) with panel (optional):

Review: _____ (Branch Chief) CSDS (Branch Code) 12/22/06 (Date)

Final Review: _____ (Division Director) DORMP (Branch Code) 12/26/06 (Date)

Revised:4/2/03

4

MEMO RECORD

DATE: December 22, 2006

FROM: Theodore R. Stevens, Supervisory Biomedical Engineer, HFZ-410

TO: The Record, K060415/S002

SUBJECT: Medtronic Sofamor Danek PEEK Satellite Sphere, supervisory review

Common Name: Orthosis, spinal intervertebral fusion, solid sphere
Trade Name: SATELLITE™ Spinal System
Class: unclassified
Product Code: NVR
☒ 510(k) summary ☐ 510(k) statement
☒ Truth/Accuracy statement
☒ Indications for Use: *"The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervetebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft."*

concur BDP 12/26/06

This device is for prescription use.

Contact/Telephone number: Christine Scifert
Tel: 901.396.3133
Fax: 901.346.9738

Claimed equivalent devices: K051320 - SATELLITE™ Spinal System,

(b) (5) [redacted]

Supervisory recommendation: SU – Substantially Equivalent, with limitations.

Limitation: "The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established."

Reason for limitation: K051320 received SU letter. Likelihood of off-label use for non-fusion indications (b) (4) [redacted] ***. Without fusion, device is likely to migrate or be expelled.***

6

Basis of Recommendation:

Intended Use: See "Indications for Use" above. The indications for use are identical to those for the CoCr alloy version of the device cleared under K051320.

Device Description: Spheres, 11, 12, 13, 14, 15 or 16mm in diameter (previously-proposed 10mm sizes removed in this supplement), with a small threaded hole and counterbore hole for insertion of implantation instrumentation. A small tantalum wire marker is press-fit above the insertion hole. The dimensions of the spheres are identical to a subset of the cobalt-chromium alloy SATELLITE™ Spinal System cleared under K051320, which was also available in 9.5, 10, 17, 18 and 19mm diameters. Identical instrumentation is used for implantation.

Material: PEEK-OPTIMA LT1 per ASTM F2026. Material is identical to that of K021791 VERTE-STACK™ Spinal System. The PEEK SATELLITE™ device is also manufactured at the same site, using the same methods, as the VERTE-STACK. A

Sterilization: Identical processing to PEEK VERTE-STACK™ K023570:
Method: Gamma Sterilization

(b) (4) [redacted]

Response to deficiencies (see AI letter dated April 5, 2006 for full text of deficiencies):

1. Clinical data request

Response: The sponsor states accurately that the geometry of the PEEK devices is identical to that of the metallic versions. They also point out that several other spinal implants have been cleared or approved for changes from metal alloys to PEEK, without the need for clinical data. They also point out that the subsidence and pushout testing results for are comparable (though slightly superior) for the PEEK vs. CoCr versions of the device.

Although we do not currently have clinical data for the PEEK version of the SATELLITE™ Spine System, many other implants have been cleared without clinical data, on the basis of mechanical testing showing adequate mechanical properties for the physiological loads experienced. Because this device is essentially a solid PEEK sphere, it can support loads much higher than the surrounding bone. According to the information provided in support of pre-amendments status for the original Harmon Sphere predicate, the spheres are expected to subside within several weeks after implantation. The sponsor has provided bench data showing that, while a slightly higher

load was required for subsidence of the 11mm PEEK spheres compared to CoCr spheres in foam, the loads were comparable (b) (4) [redacted] Pushout testing of the PEEK spheres was also higher (b) (4) [redacted] Based on this testing, and the successful history of other PEEK spinal devices such as VBR's, I do not believe there is a reasonable expectation that the PEEK version will migrate or expulse at a higher rate than the CoCr version of the SATELLITE™ system.

2. Compression, wear testing:

Response adequate, per J. Peck memo dated 12/22/06.

3. Identification of specific materials: adequate response, per J. Peck memo dated 12/22/06

Recommendation: ***SU – Substantially Equivalent, with limitations.***

Theodore R. Stevens

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K060415/S002

Reviewer: Theodore R. Stevens

Division/Branch: DGRND/OSDB

Device Name: SATELLITE™ Spinal System

Product To Which Compared (510(K) Number If Known): K051320 - SATELLITE™ Spinal System; K021791 VERTE-STACK™ Spinal System (for material)

		YES	NO	
1.	Is Product A Device	✓		If **NO** = Stop
2.	Is Device Subject To 510(k)?	✓		If **NO** = Stop
3.	Same Indication Statement?	✓		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?		✓	If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?	✓		If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 ***If YES = Stop SE***
8.	New Types Of Safety Or Effectiveness Questions?		✓	If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?	✓		If **NO** = Stop **NE**
10.	Performance Data Available?	✓		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PREVIOUS PAGE AS NEEDED

1. Explain why not a device: NOT APPLICABLE

2. Explain why not subject to 510(k): NOT APPLICABLE

3. How does the new indication differ from the predicate device's indication: *N/A*

4. Explain why there is or is not a new effect or safety or effectiveness issue: *NA*

5. Describe the new technological characteristics: *Subject device is manufactured from PEEK Optima LT-1 polymer instead of cobalt chromium alloy*

6. Explain how new characteristics could or could not affect safety or effectiveness: *Biocompatibility, wear, mechanical characteristics could all affect performance*

7. Explain how descriptive characteristics are not precise enough: N/A

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: *Biocompatibility, wear, and mechanical strength are all standard questions for spinal implants.*

9. Explain why existing scientific methods can not be used: N/A

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b) (5)

From: Stevens, Ted
Sent: Friday, December 22, 2006 7:15 PM
To: Buch, Barbara D
Cc: Melkerson, Mark N.; Peck, Jonathan H
Subject: K060415 Satellite Spinal System

Barb: I have reviewed Jonathan's memo. I agree that there was not much clinical data initially to support the pre-amendments fusion device, and that we need to be vigilant with these devices regarding off label use. Based on the information in the file, and how we have reviewed other PEEK devices, I do not believe there is sufficient concern regarding additional risk of expulsion or migration to ask for clinical data, and am recommending SU (SE with limitations). I have placed a copy of my supervisory memo in the file on top of Jonathan's memo, and have prepared an SU (b) (5) [redacted]

Copies of the letter and memo are attached, and on the P: drive. << File: K060415 S001 PEEK Satellite supervisory memo.doc >> << File: K060415 PEEK Satellite SU letter.DOC >>

Theodore R. Stevens
Chief, Orthopedic Spine Devices Branch (OSDB)
Division of General, Restorative & Neurological Devices
Office of Device Evaluation, FDA
(240) 276-3676
(240) 276-3602 (fax)
theodore.stevens@fda.hhs.gov

Julie "Brandi" Stuart
120L – 301-594-1190x144

12/29 - faxed firm awaiting resp - Brandi
1/4 - received fax resp fr firm
1/4 - sent to DBT for Sig

SE w/Limitations
(SU)

K060415

PRO CODE: NVR

3 Total Submissions:

1 – SE with Limitations (for this same firm)
2 – Under Review

Hi Donna Bea,

I already faxed the firm, since they have received a SU for this same device type before.

Let me know if you need anything else.

Brandi

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Medtronic

1800 Pyramid Place
Memphis, TN 38132
Tel:901-3992042 Fax: 901-346-0738

TELEFAX TRANSMISSION

To: Brandi Stuart

Fax Number: 240-276-4009

From: Christine Seifert **Linda C. Baker / MSD**

Date: 1/3/07

Subject: SE Ltr with Limitations K060415 response

Total Transmitted Pages: 4pgs

Remarks:

☐ **Urgent** ☐ **Reply ASAP** ☐ **For Your Review** ☐ **Please Comment**

Message:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Christine Scifert 1/3/07

Re: K060415/S1
Trade Name: SATELLITE® Spinal System
Regulatory Class: Unclassified
Product Code: NVR
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> "The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

DRAFT

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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February 2006

510(k) Number (if known): K060415

Device Name: SATELLITE™ Spinal System

Indications for Use:

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

DRAFT

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Quenn

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060415/c

000039

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Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Program Operations Staff
9200 Corporate Blvd.
Rockville, MD 20850

Fax Number: 240-276-4009
Phone Number: 240-276-4020

Program Operations Staff

Fax

To:	Christine Scifert	**From:**	Brandi Stuart
Fax:	901-346-9738	**Pages:**	4 (including cover page)
Email	christine.scifert@medtronic.com	**Date:**	12.29.06
Re:	SE Ltr with Limitations – k060415	**CC:**	

☑ **Urgent** ☑ **For Review** ☐ **Please Comment** ☑ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Attached is a draft SE letter that contains limitations language concerning your clearance. Please review and if you concur please fax back a written affirmation to the language in the letter. You may sign and date directly on the draft ltr to affirm or deny.

If you have any questions please contact me at the number above.

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Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Program Operations Staff
9200 Corporate Blvd.
Rockville, MD 20850

Fax Number: 240-276-4009
Phone Number: 240-276-4020

Program Operations Staff

Fax

To:	Christine Scifert	**From:**	Brandi Stuart
Fax:	901-346-9738	**Pages:**	4 (including cover page)
Email	christine.scifert@medtronic.com	**Date:**	12.29.06
Re:	SE Ltr with Limitations – k060415	**CC:**	

☑ **Urgent** ☑ **For Review** ☐ **Please Comment** ☑ **Please Reply** ☐ **Please Recycle**

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If you have any questions please contact me at the number above.

* * * COMMUNICATION RESULT REPORT (DEC. 29. 2006 2:46PM) * * *

FAX HEADER 1: FDA-CDRH-ODE-POS
FAX HEADER 2:

TRANSMITTED/STORED : DEC. 29. 2006 2:45PM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
1067 MEMORY TX		MEDTRONIC SOFMAMOR	OK	4/4

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Program Operations Staff
9200 Corporate Blvd.
Rockville, MD 20850

Fax Number: 240-276-4009
Phone Number: 240-276-4020

Program Operations Staff

Fax

To:	Christine Scifert	**From:**	Brandi Stuart
Fax:	901-346-9738	**Pages:**	4 (including cover page)
Email	christine.scifert@medtronic.com	**Date:**	12.29.06
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If you have any questions please contact me at the number above.

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510(k) MEMORANDUM

To:	K060415/S1
From:	Jonathan H. Peck, Mechanical Engineer ODE/DGRND/Orthopedic Devices Branch
Date:	November 27, 2006
Subject:	Satellite Spinal System Product Code: NVR Unclassified, Pre-amendments
Firm:	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, TN 38132
Contact:	Richard Treharne Phone: (219) 396-3133 Fax: (901) 346-9738
Decision:	**AI (Hold)**

JP 12/22/06

Recommendation:
I recommend the PEEK Satellite Sphere be placed on hold because the sponsor has not provided clinical evidence that the PEEK device (or the previously cleared cobalt chrome device) provide an adequate adjunct to fusion. As stated in Deficiency #1 below, "The overall effect that this change in material could have on the performance of the Satellite Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited understanding of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the performance of the device." Therefore I recommend we send an AI letter to the sponsor containing the deficiency below.

Summary:
Medtronic obtained clearance for the cobalt chrome Satellite Spinal System under K051320 for fusion from L3 to S1. The previously cleared Satellite Spinal System is a cobalt chrome sphere (which comes in several sizes) that is intended to be placed between adjacent vertebral bodies. This system obtained clearance because the sponsor was able to show that the cobalt chrome spheres were essentially identical to the pre-amendments Harmon Spheres. The sponsor was able to establish that the Harmon Spheres are a valid predicate for fusion from L3 to S1. The sponsor now wishes to add additional spheres to the Satellite Spinal System manufactured from PEEK-OPTIMA LT1. We have little knowledge of how a material change could affect the performance of this device as an adjunct to fusion. Therefore, I believe clinical data are necessary to demonstrate the substantial equivalence (safety and effectiveness) of the new PEEK devices.

The sponsor has provided a letter from Dr. Fernstrom to Dr. Mayer which describes Dr Fernstrom's use of the "steel ball" in 195 patients. The article does not describe fusion procedures or fusion outcomes. The sponsor has also provided an article by Dr. Alvin McKenzie describing 103 cases where the sphere was implanted (some cases with multiple levels) for non-fusion as well. This data does not support the use of the PEEK sphere for the indication sought. Therefore, I will again ask the company to provide clinical data to justify the change from Chromium to PEEK.

Deficiency:
In our April 5, 2006 letter you were asked to provide clinical data to demonstrate that the PEEK Satellite Spinal System performs equivalently to a legally marketed predicate device as an adjunct to fusion. Your device has a unique spherical design as compared to other legally marketed fusion devices. Therefore, the effect that this change in material could have is not well understood. We believe the increased flexibility of the PEEK device may make it more susceptible to certain adverse events such as device migration or device expulsion for which there are no universally accepted preclinical test methods. The clinical information you provided details use of the steel sphere for an off-label non-fusion indication. No clinical information was provided on the PEEK device for the indication sought. Therefore, please provide clinical

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data that demonstrates the PEEK sphere performs equivalently to a legally marketed fusion device as an adjunct to fusion. We would expect the clinical data set to demonstrate that use of the device in combination with bone graft (as indicated) results in radiographic fusion and that the subject device does not yield significantly higher rates of migration, expulsion or other adverse events than the legally marketed device. Please be advised that prior to initiating a clinical study in the United States that you must submit an IDE application to the FDA for review.

Reasons for AI:
The PEEK device could have a higher expulsion rate than the Chromium device. Current expulsion testing does not represent the physiological environment and may not adequately characterize a specific device's propensity to expulse. At the most recent ASTM meeting in Atlanta (2006), there were discussions on improving this test, but no clear cut answer to the problem at this time. So despite the fact that the sponsor showed the device to perform equivalently in the expulsion testing, since the test methods may not be adequate, clinical data is the only way to assess this issue.

In the same line of thinking, the PEEK device may have a higher rate of migration. The unique spherical design combined with the higher flexibility of the device material could lead to a higher rate of device migration.

These reasons combined with the overall lack of information on how this device performs as an adjunct to fusion lead to the request for clinical data on the PEEK device as an adjunct to fusion.

Note: This file was converted from a Special 510(k) to a traditional for the following reason: *The Satellite Spinal System is unclassified, pre-amendments. The sponsor is now proposing a change in the material of the device to PEEK. Since we have not seen a device of this type that is manufactured from PEEK, this change represents a fundamental change in technology and therefore, the application is not appropriate for the Special 510(k) program.*

Discussion with Management:
(b) (5) [redacted]

Spine Team Meeting:
I brought this file to Spine Team meeting on November 29, 2006. In attendance were Ted Stevens, Jodi Anderson, Sergio de del Castillo, Ann Ferriter, Nadine Sloan, Genevieve Hill, Mike Courtney, Jismi Jose and Bryce Whited. We discussed the issue of modifying this unclassified, pre-amendments device. It was agreed upon by the team that we could not fully understand the affect that this change in material would have on the device's performance without good clinical data on either the original cobalt chromium device or the PEEK sphere. (b) (5) [redacted]

(b) (5) [redacted]

Previous Deficiencies and Sponsor's Response (S1):

1. You propose the addition of spheres manufactured from PEEK-OPTIMA LT1 to the Satellite Spinal System. This system has unique geometry as compared to other legally marketed fusion devices and you have not provided clinical information on the safety and effectiveness of this device as an adjunct to fusion. You have provided data from two bench tests, subsidence and push-out, which demonstrate that the PEEK Satellite Spinal System performs differently from the cobalt chrome predicate. The overall effect that this change in material could have on the performance of the Satellite Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited understanding of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the performance of the device. Therefore, please provide clinical data that demonstrates equivalence in terms of safety and effectiveness of the PEEK Satellite Spinal System for the indication sought. Please be advised that prior to initiating a clinical trial in the United States you must submit an investigational device exemption (IDE) application for review by the FDA.

Sponsor's Response (S1):
The sponsor states that they are confused by FDA's question. The sponsor believes that since the clearance of the cobalt chromium harmon sphere was granted, that the change to PEEK is justified due to the long history of PEEK in the spine. The sponsor has referenced devices such as the VERTE-STACK Spinal System, the CD HORIZON, and the PEEK LT-CAGE as examples of PEEK devices (or devices with PEEK components) that have been cleared of approved. The LT-CAGE and the VERTE-STACK are the most relevant in that they are used in the disc space. The sponsor states that clinical data was never required to gain clearance of the LT-CAGE of the VERTE-STACK devices. The sponsor also argues that mechanical testing was offered to compare the PEEK LT-CAGE to the titanium counterpart and that the PEEK device was outperformed by the titanium device.

The sponsor has provided the "clinical data" that was provided with the original Satellite System submission. This data consists of the following:

A Letter from Dr. Fernstrom to Dr. Mayer:
In this letter, Dr. Fernstrom describes his use of the "steel ball" in the lumbar and cervical spine. The letter describes problems with migration and subsidence:

> "Migration of steel ball occurs always three weeks after operation and depends on too big steel ball."
>
> "There is no erosion of vertebrae but the steel ball has sinking into the vertebrae body, slight 74%, obvious 13% and totally 0.7% and in 12% the height of the disc has not changed. This figures are from 164 steel balls observed during 5-7 years after operation."

Reviewer Comments:
(b) (5) [redacted]

A Paper: *Fernstrom Intervertebral Disc Arthroplasty: A Long-Term Evaluation:*
This article describes the use of metal spheres in 103 patients for *arthroplasty.*

Reviewer Comments:
This paper is therefore irrelevant to the discussion as the clinical data presented is not for the intended use of the subject device.

A power-point presentation of the use of the metal sphere as a disc arthroplasty:
Again, this is a presentation on the use of the device in disc arthroplasty.

Reviewer Comments:
Therefore the data presented is irrelevant this submission.

An Affidavit from Alvin H. McKenzie, M.D.:
Dr. McKenzie stated that the spinal sphere was used as a fusion and arthroplasty device.

Reviewer Comments:
This affidavit was not evidence enough to allow the arthroplasty intended use in the original Satellite submission and it certainly does not contain compelling clinical data.

Deficiency:
2. You have provided results of subsidence testing and push-out testing of your worst case PEEK device. The PEEK device exhibited a higher subsidence load and a higher push-out load than the predicate cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that are associated with changing the device material from cobalt chrome to PEEK. The PEEK device could fail at low compression loads (static and fatigue) as compared to a legally marketed predicate device. In addition, the PEEK device could be subject to wear. Therefore, please:

    a. Provide results of static and dynamic compression testing of the worst case PEEK device. Please compare the results of these tests to a legally marketed predicate fusion device and provide a physiologic justification showing that the strength exhibited by the device in static compression and compression fatigue is adequate.

Sponsor's Response (S1):
The sponsor performed static and dynamic compression testing on the device per ASTM F1077. The 11mm device was chosen as worst case. The sponsor has removed the 10mm implant from the submission (An updated implant listing has been provided). The 11mm device ran out to (b) (4) under a (b) (4) without fracture or failure.

Five devices were tested in static compression. The average yield load was (b) (4) and the average stiffness was (b) (4).

Reviewer Comments:
The device performed adequately in static compression and compression fatigue. This deficiency is adequately resolved.

    b. Provide results of wear testing on the worst case PEEK device. This test should mimic abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with the literature.

Sponsor's Response (S1):
All static compression and compression fatigue testing was performed in solution. The devices were weighed and it was found that all specimens gained weight during testing. The sponsor concluded that this meant that no excessive amounts of wear debris were generated during testing.

The fatigue specimens gained (b) (4) respectively.

Reviewer Comments:
The wear testing (b) (4)

compression. However, I do not believe that wear is a huge concern given the design and intended use of the device. The device is simply a sphere. Since it is intended to be used as a cage, the device will probably not experience much wear. Therefore, I believe this deficiency is adequately resolved.

Deficiency:

3. You state that the subject devices are manufactured from PEEK-OPTIMA LT1 and tantalum. However, you have not provided any specific information on the materials. Please provide the manufacturer of the materials and any standards to which the materials conform. Please identify a predicate device which utilizes these same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility or material properties of the device.

Sponsor's Response (S1):

The sponsor states that the materials are used in the predicates as well. The PEEK is identical to the material used in the VERTE-STACK and the CD HORIZON. The Tantalum material is identical to material used in the same predicates. The tantalum is per ASTM F560.

Reviewer Comments:

This deficiency is adequately resolved.

Administrative Requirements:

This submission contains a Truthful and Accurate Statement, a 510(k) Summary and an Indications for Use page.

Internal Administrative Form:

		YES	NO
1.	Did the firm request expedited review?		X
2.	Did we grant expedited review?		N/A
3.	Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4.	If, not, has POS been notified?		N/A
5.	Is the product a device?	X	
6.	Is the device exempt from 510(k) by regulation or policy?		X
7.	Is the device subject to review by CDRH?	X	
8.	Are you aware that this device has been the subject of a previous NSE decision?		X
9.	If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		N/A
10.	Are you aware of the submitter being the subject of an integrity investigation?		X
11.	If, yes, consult the ODE Integrity Officer.		N/A
12.	Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		N/A

Substantial Equivalence Decision Making Checklist:

		YES	NO	
1.	Is the product a device?	X		NO then Stop
2.	Is the device subject to 510(k)?	X		NO then Stop
3.	Is the indication statement the same?	X		YES then Go To 5
4.	Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5.	Does the device have the same technological characteristics?		X	YES then Go To 7
6.	Could the new characteristics affect safety and effectiveness?	X		YES then Go To 8
7.	Are the descriptive characteristics precise enough?			NO then Go To 10 YES then SE
8.	Are there new types of safety and effectiveness questions?		X	YES then NSE
9.	Do accepted scientific methods exist to test the impact of the new characteristics?	X		NO then NSE
10.	Is performance data available?	X		NO then Request Data
11.	Does the performance data demonstrate substantial equivalence?		X	FINAL DECISION: **AI (Hold**

Explanations for "yes" responses to questions 4, 6, 8, and 11, and every "no" response in the Substantial Equivalence (SE) Decision Making Checklist:

5. Does the device have the same technological characteristics?

No. The change in material from cobalt chrome to PEEK represents a change in the fundamental technology of the device since it is unclassified, preamendments.

6. Could the new characteristics affect safety and effectiveness?

Yes. Since this device design is quite unique, as compared to other interbody fusion devices, we are not sure what affect this material change could have on the safety and effectiveness of the device.

10. Is performance data available?

The sponsor provided data (discussed above) on the use of metal spinal spheres used for spinal arthroplasty. None of the data is compelling and none of the data suggests that the use of a PEEK sphere as an adjunct to fusion would be substantially equivalent to any cleared fusion system including the cobalt chromium spheres.

11. Does the performance data demonstrate substantial equivalence?

No. The data provided is mostly on the use of the device for disc arthroplasty. Either way, the data does not support the use of a PEEK sphere as an adjunct to fusion.

PREVIOUS REVIEW:

Device Description:
The previously cleared Satellite Spinal System (K051320) was a series of cobalt chrome spheres intended to be placed between adjacent vertebral bodies as an adjunct to fusion. The sponsor now wishes to modify the material to PEEK.

The subject devices are essentially PEEK spheres which have cylindrical cutouts for insertion instrumentation. The device also features a 0.029 diameter cylindrical tantalum marker that is press fit into a cylinder above the main instrument insertion hole.

Sizes:
The devices come in 7 sizes ranging from 10mm to 16mm in 1mm increments.

Reviewer Comments:
The main change being made to the system is a change in the material from cobalt chrome to PEEK. We were not comfortable clearing the original Satellite System (K051320) manufactured from cobalt chrome because there is limited clinical information on the device and the results do not lead to the conclusion that the device is successful in aiding fusion. Our hand was forced to clear the previous Satellite System because it was essentially identical to a pre-amendments device called the Harmon Sphere. Since the Satellite System is unclassified and pre-amendments, the change in materials represents a fundamental change in technology. I believe that we do not know enough about this device design to make a determination with preclinical information as to how the device will perform in vivo. Therefore, we will be requesting clinical data for this submission.

Deficiency:
You propose to change the material of the spheres in the SATELLITE Spinal System to PEEK-OPTIMA LT1. We are unaware of a predicate device manufactured from PEEK with a spherical design that has been cleared for the indication you seek. We are also unaware of the affects this change in material could have on the performance of the device. You have provided results for two bench tests: subsidence and push-out testing. The PEEK device had a higher subsidence load and a higher push-out load than the cobalt chrome device. However, the results of the subsidence testing are difficult to interpret as you report the load at

which the device has fully subsided into the foam blocks. The definition of failure in subsidence should be prior to the device fully subsiding. In addition, we feel that the push-out test performed does not mimic the way the device may expulse in vivo. We feel that, given our limited understanding of how this device will perform in vivo, clinical data is the only way to assess this material change. Therefore, please provide clinical data that demonstrates the safety and effectiveness of the PEEK SATELLITE Spinal System as an adjunct to fusion. This data should address the risks of expulsion and subsidence and show that the device is an effective adjunct to fusion as compared to a legally marketed predicate device. Please be advised that prior to initiating a clinical trial in the US, you must submit an investigational device exemption (IDE) application for review by the FDA.

Materials:
The sponsor seeks clearance for Satellite Devices manufactured from medical grade PEEK-OPTIMA LT1. These devices also have tantalum markers.

Reviewer Comments:
The sponsor has not provided sufficient material information. The sponsor should identify a predicate device that utilizes the exact same material processed in exactly the same manner.

Deficiency:
You state that the subject devices are manufactured from PEEK-OPTIMA LT1 with tantalum markers. However, you have not provided any specific information on the materials. Please provide the manufacturer of the material and any standards to which the materials conform. It is helpful if you identify a predicate device which utilizes this same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility of material properties of the device/materials.

Intended Use:
The indications have not changed from the predicate:

The Satellite Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and design solely for holding bone parts in alignment while they heal. The Satellite Spinal System is intended to be used with bone graft.

Sterilization:
The following instructions are provided in the package insert:

"Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, there products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

Method	Cycle	Temperature	Exposure Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes
Steam	Gravity	250°F (121°C)	30 minutes
Steam	Gravity	273°F (134°C)	20 minutes

Reviewer Comments:
The device will be supplied sterilized via gamma sterilization that is identical to the previously cleared device.

Labeling:
Draft Package Label:
The draft package label is adequate and contains:

- Company Name, Address, Phone #
- Device Name, Size and Quantity
- "Sterile" and "Sterility is assured only when package is undamaged"
- Material Name
- Ref # and Lot #

Draft Package Insert:
The draft package insert contains the following:

- Product description
- Contraindications, Possible Adverse Events, Warnings
- Operative Instructions
- Packaging, cleaning and decontamination
- Sterilization
- Product complaints information
- Company Name, Address and Phone#

Testing:
The sponsor performed two tests on the subject devices: push out testing and subsidence testing.

Worst Case Rationale: The sponsor tested the 10mm implants as they are the smallest PEEK size available, thus making it the worst case size in subsidence, but perhaps not pushout.

Push-Out Testing:
Methods-
(b) (4) [redacted]

Results-
(b) (4) [redacted]

Reviewer Comments:
The sponsor concludes that the PEEK devices have a statistically significantly higher push out resistance. However, it is difficult to draw conclusions with only a (b) preload. The sponsor has nicely summarized our concerns with this device in their methods for this test. When a (b) preload was used, subsidence occurred due to the spherical geometry of the device. This is also what we would expect to happen in vivo.

This is why we will be requesting clinical data for this design change despite the fact that the PEEK device outperformed the predicate in this test.

Subsidence Testing:

Methods-

(b) (4)

Results-

Specimen	Peak Load (N)
(b) (4)	

Reviewer Comments:

(b) (4)

Risk Assessment:

This document was originally a Special 510(k) so the sponsor supplied the following risk analysis:

Change	Risk	Verification	Acceptance Criteria	Results of Verification
Change in material from cobalt chrome to PEEK	Material change could negatively impact subsidence or push-out.	Subsidence test and Push-out test of 10mm PEEK (worst case) and 10mm Cobalt Chrome (worst case)	Subsidence and Push-out Tests must demonstrate PEEK device to be substantially equivalent to predicate SATELLITE device.	Testing demonstrated that PEEK was greater in Subsidence (b) (4) (b) (4) (b) (4) resistance than predicate SATELLITE device.

Reviewer Comments:

The sponsor has not identified all of the potential risks in switching the device material from CoCr to PEEK. As with any cage or VBR, the sponsor should address the risk of failure in static compression and compression fatigue. Given the design of the product (a sphere) and the fact that it is not intended to resist torsional loads, I do not see a need for static torsional or torsional fatigue testing.

Deficiency:

3. You have provided results of subsidence testing and push-out testing of your worst case PEEK device as compared to the pre-amendments cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that come along with changing the device from cobalt chrome to PEEK. We believe that the PEEK device could fail at lower compression loads (static and fatigue). In addition, we believe the PEEK device could be subject to excessive wear as the vertebral endplates move with respect to one another. Therefore, please:

    c. Provide results of static and dynamic compression testing of the worst case PEEK device. Please provide results of this testing to a legally marketed predicate device and provide a physiologic rationale for the strength of the device in static compression and compression fatigue.

    d. Provide results of wear testing on the worst case PEEK device. This test should mimic the abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with literature.

Predicates used to support of SE:

The sponsor references the unclassified, pre-amendments Satellite Spinal System (K051320) as a predicate for the subject PEEK devices. The following comparison chart was provided:

	Predicate SATELLITE device	Subject SATELLITE device
Intended Use/Indications for Use	To help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal.	Identical
Implant Size Range	9.5mm – 19mm	Inclusive – 10mm – 16mm
Levels of Attachment	L3-S1	Identical
Surgical technique	Anterior Approach	Identical
Material	Cobalt Chrome	PEEK-Optima LT1/Tantalum
Sterilization Method	Gamma	Identical
Fundamental Scientific Tech.	Spherical implant inserted into the disc space.	Identical

End of Review (JHP)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Jonathan Peck

Subject: 510(k) Number K060415

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☒ YES	☐ NO
Is this a prescription device?	☒ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Unclassified, NVR

Additional Product Code(s) with panel (optional):

Review: _____ OSDB 4/4/06
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:4/2/03

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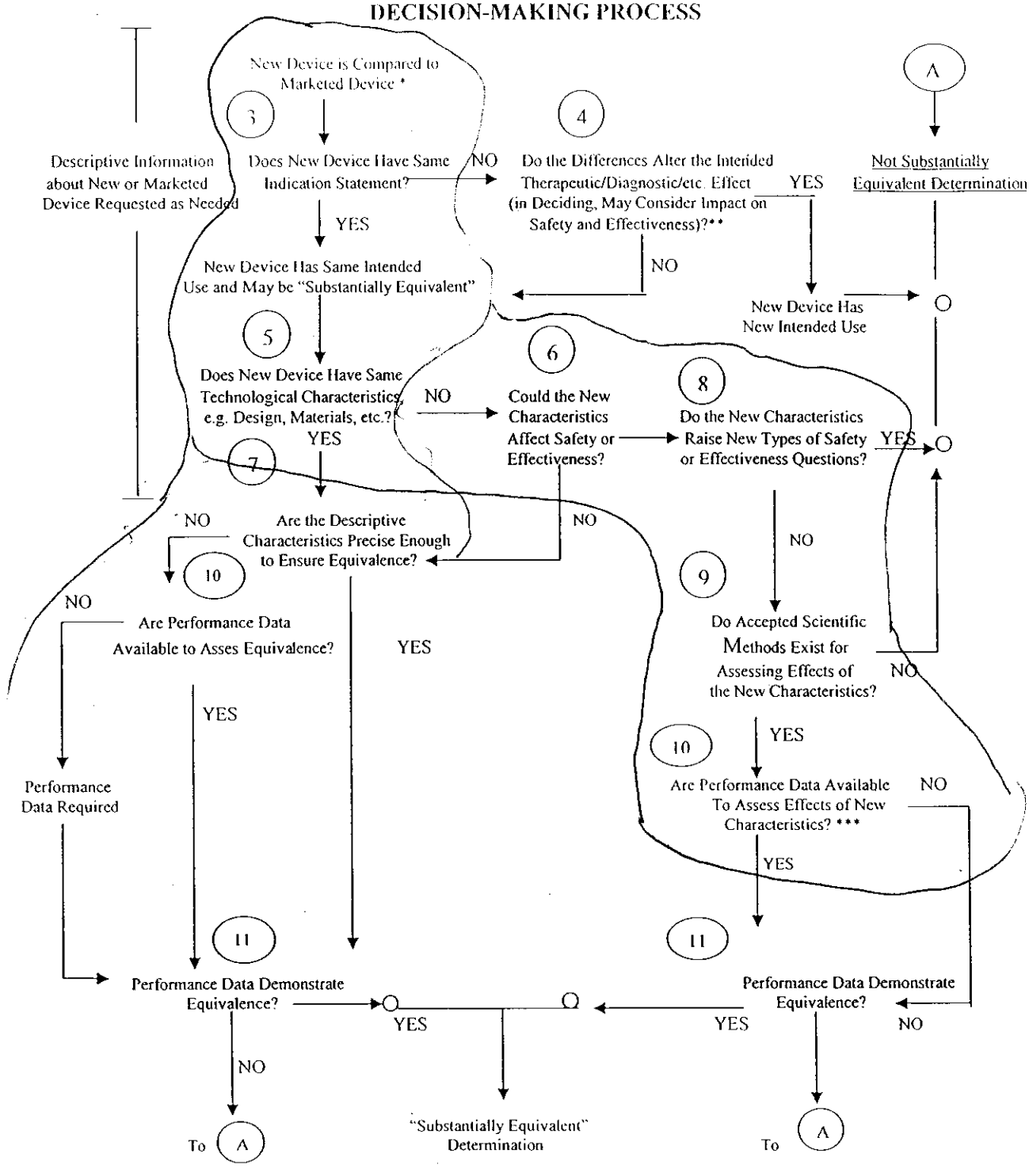
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: k060415

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No
Reviewer: Jonathan Peck
Concurrence by Review Branch: _____

Date: _____

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510(k) MEMORANDUM

To:	K060415
From:	Jonathan H. Peck, Mechanical Engineer ODE/DGRND/Orthopedic Devices Branch
Date:	March 23, 2006
Subject:	Satellite Spinal System Product Code: NVR Unclassified, Pre-amendments
Firm:	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, TN 38132
Contact:	Richard Treharne Phone: (219) 396-3133 Fax: (901) 346-9738
Decision:	**Hold (AI)**

JP 9/4/06

Recommendation:
I recommend this file be placed on hold so that the sponsor can address the deficiencies listed below.

Summary:
Medtronic obtained clearance for the cobalt chrome Satellite Spinal System under K051320 for fusion from L3 to S1. The previously cleared Satellite Spinal System is a cobalt chrome sphere (which comes in several sizes) that is intended to be placed between adjacent vertebral bodies. This system obtained clearance because the sponsor was able to show that the cobalt chrome spheres were essentially identical to the pre-amendments Harmon Spheres. The sponsor was able to establish that the Harmon Spheres are a valid predicate for fusion from L3 to S1. The sponsor now wishes to add additional spheres to the Satellite Spinal System manufactured from PEEK-OPTIMA LT1. We have little knowledge of how a material change could affect the performance of this device as an adjunct to fusion. Therefore, I believe clinical data is necessary to demonstrate the safety and effectiveness of the new PEEK devices. Please see the deficiencies that follow.

Note: This file was converted from a Special 510(k) to a traditional for the following reason: *The Satellite Spinal System is unclassified, pre-amendments. The sponsor is now proposing a change in the material of the device to PEEK. Since we have not seen a device of this type that is manufactured from PEEK, this change represents a fundamental change in technology and therefore, the application is not appropriate for the Special 510(k) program.*

The conversion form is attached.

Attached:
Memo for K051320 for reference.
Conversion form (Special to Traditional)
Email documentation

Combined Deficiencies as they appear in the AI Letter to the Sponsor:

1. You propose the addition of spheres manufactured from PEEK-OPTIMA LT1 to the Satellite Spinal System. This system has unique geometry as compared to other legally marketed fusion devices and you have not provided clinical information on the safety and effectiveness of this device as an adjunct to fusion. You have provided data from two bench tests, subsidence and push-out, which demonstrate that the PEEK Satellite Spinal System performs differently from the cobalt chrome predicate. The overall effect that this change in material could have on the performance of the Satellite Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited understanding of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the performance of the device. Therefore, please provide

clinical data that demonstrates equivalence in terms of safety and effectiveness of the PEEK Satellite Spinal System for the indication sought. Please be advised that prior to initiating a clinical trial in the United States you must submit an investigational device exemption (IDE) application for review by the FDA.

2. You have provided results of subsidence testing and push-out testing of your worst case PEEK device. The PEEK device exhibited a higher subsidence load and a higher push-out load than the predicate cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that are associated with changing the device material from cobalt chrome to PEEK. The PEEK device could fail at low compression loads (static and fatigue) as compared to a legally marketed predicate device. In addition, the PEEK device could be subject to wear. Therefore, please:

   a. Provide results of static and dynamic compression testing of the worst case PEEK device. Please compare the results of these tests to a legally marketed predicate fusion device and provide a physiologic justification showing that the strength exhibited by the device in static compression and compression fatigue is adequate.

   b. Provide results of wear testing on the worst case PEEK device. This test should mimic abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with the literature.

3. You state that the subject devices are manufactured from PEEK-OPTIMA LT1 and tantalum. However, you have not provided any specific information on the materials. Please provide the manufacturer of the materials and any standards to which the materials conform. Please identify a predicate device which utilizes these same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility or material properties of the device.

Administrative Requirements:
This submission contains a Truthful and Accurate Statement, a 510(k) Summary and an Indications for Use page.

Internal Administrative Form:

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		N/A
3. Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4. If, not, has POS been notified?		N/A
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		N/A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		N/A
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		N/A

Substantial Equivalence Decision Making Checklist:

	YES	NO	
1. Is the product a device?	X		NO then Stop

2.	Is the device subject to 510(k)?	X		NO then Stop
3.	Is the indication statement the same?	X		YES then Go To 5
4.	Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5.	Does the device have the same technological characteristics?		X	YES then Go To 7
6.	Could the new characteristics affect safety and effectiveness?	X		YES then Go To 8
7.	Are the descriptive characteristics precise enough?			NO then Go To 10 YES then SE
8.	Are there new types of safety and effectiveness questions?		X	YES then NSE
9.	Do accepted scientific methods exist to test the impact of the new characteristics?	X		NO then NSE
10.	Is performance data available?		X	NO then Request Data
11.	Does the performance data demonstrate substantial equivalence?			FINAL DECISION:

Explanations for "yes" responses to questions 4, 6, 8, and 11, and every "no" response in the Substantial Equivalence (SE) Decision Making Checklist:

5. Does the device have the same technological characteristics?

No. The change in material from cobalt chrome to PEEK represents a change in the fundamental technology of the device since it is unclassified, preamendments.

6. Could the new characteristics affect safety and effectiveness?

Yes. Since this device design is quite unique, as compared to other interbody fusion devices, we are not sure what affect this material change could have on the safety and effectiveness of the device.

10. Is performance data available?

No. The sponsor will need to provide additional preclinical (compression and wear testing) and clinical data.

Device Description:
The previously cleared Satellite Spinal System (K051320) was a series of cobalt chrome spheres intended to be placed between adjacent vertebral bodies as an adjunct to fusion. The sponsor now wishes to modify the material to PEEK.

The subject devices are essentially PEEK spheres which have cylindrical cutouts for insertion instrumentation. The device also features a 0.029 diameter cylindrical tantalum marker that is press fit into a cylinder above the main instrument insertion hole.

Sizes:
The devices come in 7 sizes ranging from 10mm to 16mm in 1mm increments.

Reviewer Comments:
The main change being made to the system is a change in the material from cobalt chrome to PEEK. We were not comfortable clearing the original Satellite System (K051320) manufactured from cobalt chrome because there is limited clinical information on the device and the results do not lead to the conclusion that the device is successful in aiding fusion. Our hand was forced to clear the previous Satellite System because it was essentially identical to a pre-amendments device called the Harmon Sphere. Since the Satellite System is unclassified and pre-amendments, the change in materials represents a fundamental change in technology. I believe that we do not know enough about this device design to make a determination with preclinical information as to how the device will perform in vivo. Therefore, we will be requesting clinical data for this submission.

Deficiency:
You propose to change the material of the spheres in the SATELLITE Spinal System to PEEK-OPTIMA LT1. We are unaware of a predicate device manufactured from PEEK with a spherical design that has been cleared for the indication you seek. We are also unaware of the affects this change in material could have on the performance of the device. You have provided results for two bench tests: subsidence and push-out testing. The PEEK device had a higher subsidence load and a higher push-out load than the cobalt chrome device. However, the results of the subsidence testing are difficult to interpret as you report the load at which the device has fully subsided into the foam blocks. The definition of failure in subsidence should be prior to the device fully subsiding. In addition, we feel that the push-out test performed does not mimic the way the device may expulse in vivo. We feel that, given our limited understanding of how this device will perform in vivo, clinical data is the only way to assess this material change. Therefore, please provide clinical data that demonstrates the safety and effectiveness of the PEEK SATELLITE Spinal System as an adjunct to fusion. This data should address the risks of expulsion and subsidence and show that the device is an effective adjunct to fusion as compared to a legally marketed predicate device. Please be advised that prior to initiating a clinical trial in the US, you must submit an investigational device exemption (IDE) application for review by the FDA.

Materials:
The sponsor seeks clearance for Satellite Devices manufactured from medical grade PEEK-OPTIMA LT1. These devices also have tantalum markers.

Reviewer Comments:
The sponsor has not provided sufficient material information. The sponsor should identify a predicate device that utilizes the exact same material processed in exactly the same manner.

Deficiency:
You state that the subject devices are manufactured from PEEK-OPTIMA LT1 with tantalum markers. However, you have not provided any specific information on the materials. Please provide the manufacturer of the material and any standards to which the materials conform. It is helpful if you identify a predicate device which utilizes this same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility of material properties of the device/materials.

Intended Use:
The indications have not changed from the predicate:

The Satellite Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and design solely for holding bone parts in alignment while they heal. The Satellite Spinal System is intended to be used with bone graft.

Sterilization:
The following instructions are provided in the package insert:

"Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, there products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

Method	Cycle	Temperature	Exposure Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes
Steam	Gravity	250°F (121°C)	30 minutes
Steam	Gravity	273°F (134°C)	20 minutes

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Reviewer Comments:
The device will be supplied sterilized via gamma sterilization that is identical to the previously cleared device.

Labeling:
Draft Package Label:
The draft package label is adequate and contains:

- Company Name, Address, Phone #
- Device Name, Size and Quantity
- "Sterile" and "Sterility is assured only when package is undamaged"
- Material Name
- Ref # and Lot #

Draft Package Insert:
The draft package insert contains the following:

- Product description
- Contraindications, Possible Adverse Events, Warnings
- Operative Instructions
- Packaging, cleaning and decontamination
- Sterilization
- Product complaints information
- Company Name, Address and Phone#

Testing:
The sponsor performed two tests on the subject devices: push out testing and subsidence testing.

Worst Case Rationale: The sponsor tested the 10mm implants as they are the smallest PEEK size available, thus making it the worst case size in subsidence, but perhaps not pushout.

Push-Out Testing:
Methods-
(b) (4) [redacted]

Results-

Specimen	Peak Load (N)
(b) (4) [redacted]	

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S.D.	3.5

Reviewer Comments:
(b) (5)
[redacted]

Subsidence Testing:
Methods-
Five 10mm PEEK implants and five 10mm CoCr implants were tested. The implants were placed between two Grade 15 bone foam blocks. The foam blocks were pushed together at a rate of 10mm/min. "The foam blocks were compressed together at a rate of 10mm/min until a visible subsidence had occurred. Subsidence is normally evident in load-displacement graphs when the load has ceased to increase with a corresponding increase in displacement. This load "plateau" is indicative of the implant subsiding into the foam blocks. However, the Satellite implants never attained a load plateau, so the test continued until contact occurred between the foam blocks."

Results-

Specimen	Peak Load (N)
(b) (4) [redacted]	

Reviewer Comments:
(b) (5)
[redacted]

Risk Assessment:
This document was originally a Special 510(k) so the sponsor supplied the following risk analysis:

Change	Risk	Verification	Acceptance Criteria	Results of Verification
Change in material from cobalt chrome to PEEK	Material change could negatively impact subsidence or push-out.	Subsidence test and Push-out test of 10mm PEEK (worst case) and 10mm Cobalt Chrome (worst	Subsidence and Push-out Tests must demonstrate PEEK device to be substantially equivalent to	Testing demonstrated that PEEK was greater in Subsidence (b) (4) (b) (4)

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		case)	predicate SATELLITE device.	(b) (4) resistance than predicate SATELLITE device.

Reviewer Comments:
The sponsor has not identified all of the potential risks in switching the device material from CoCr to PEEK. As with any cage or VBR, the sponsor should address the risk of failure in static compression and compression fatigue. Given the design of the product (a sphere) and the fact that it is not intended to resist torsional loads, I do not see a need for static torsional or torsional fatigue testing.

Deficiency:

3. You have provided results of subsidence testing and push-out testing of your worst case PEEK device as compared to the pre-amendments cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that come along with changing the device from cobalt chrome to PEEK. We believe that the PEEK device could fail at lower compression loads (static and fatigue). In addition, we believe the PEEK device could be subject to excessive wear as the vertebral endplates move with respect to one another. Therefore, please:

   c. Provide results of static and dynamic compression testing of the worst case PEEK device. Please provide results of this testing to a legally marketed predicate device and provide a physiologic rationale for the strength of the device in static compression and compression fatigue.

   d. Provide results of wear testing on the worst case PEEK device. This test should mimic the abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with literature.

Predicates used to support of SE:
The sponsor references the unclassified, pre-amendments Satellite Spinal System (K051320) as a predicate for the subject PEEK devices. The following comparison chart was provided:

	Predicate SATELLITE device	Subject SATELLITE device
Intended Use/Indications for Use	To help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal.	Identical
Implant Size Range	9.5mm – 19mm	Inclusive – 10mm – 16mm
Levels of Attachment	L3-S1	Identical
Surgical technique	Anterior Approach	Identical
Material	Cobalt Chrome	PEEK-Optima LT1/Tantalum
Sterilization Method	Gamma	Identical
Fundamental Scientific Tech.	Spherical implant inserted into the disc space.	Identical

End of Review (JHP)

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Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Date: 3/2/06

Reviewer: Jonathan Peck

510(k) Number: K060415

Device Name: Satellite Spinal System

Reason for Conversion: The Satellite Spinal System is unclassified, pre-amendments. The sponsor is now proposing a change in the material of the device to PEEK. Since we have not seen a device of this type that is manufactured from PEEK, this change represents a fundamental change in technology and therefore, the application is not appropriate for the Special 510(k) program.

Division Director Concurrence/Name: (Please get this before calling or e-mailing POS)

Date of POS Concurrence (please document POS contact):

Heather Rosecrans Concurred on 3/2/06. An email documenting this is attached.

Date of Phone Conversation: I spoke with Lee Grant on 3/21/05.

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***Please add this to the file

(b) (5)

Peck, Jonathan H
From: Shulman, Marjorie G.
Sent: Thursday, March 02, 2006 11:07 AM
To: Rosecrans, Heather S.; Peck, Jonathan H; Melkerson, Mark N.; Stevens, Ted
Subject: RE: Converting K060415 - Satellite Spinal System to a Traditional

Hello,

I have converted the 510(k) and the new (90th day) due date is May 18, 2006. Please let me know if you need anything else.

Marjorie

Marjorie Shulman
Premarket Notification (510(k)) Staff
(301) 594-1190 x 132
email: marjorie.shulman@fda.hhs.gov (please note new email address)
****

From: Rosecrans, Heather S.
Sent: Thursday, March 02, 2006 10:17 AM
To: Peck, Jonathan H; Melkerson, Mark N.; Stevens, Ted
Cc: Shulman, Marjorie G.
Subject: RE: Converting K060415 - Satellite Spinal System to a Traditional

Perfect, this can be converted.

Heather S. Rosecrans
Director, 510(k) Staff
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(301) 594-1190 x143
Heather.Rosecrans@FDA.HHS.gov (Please note new email address)

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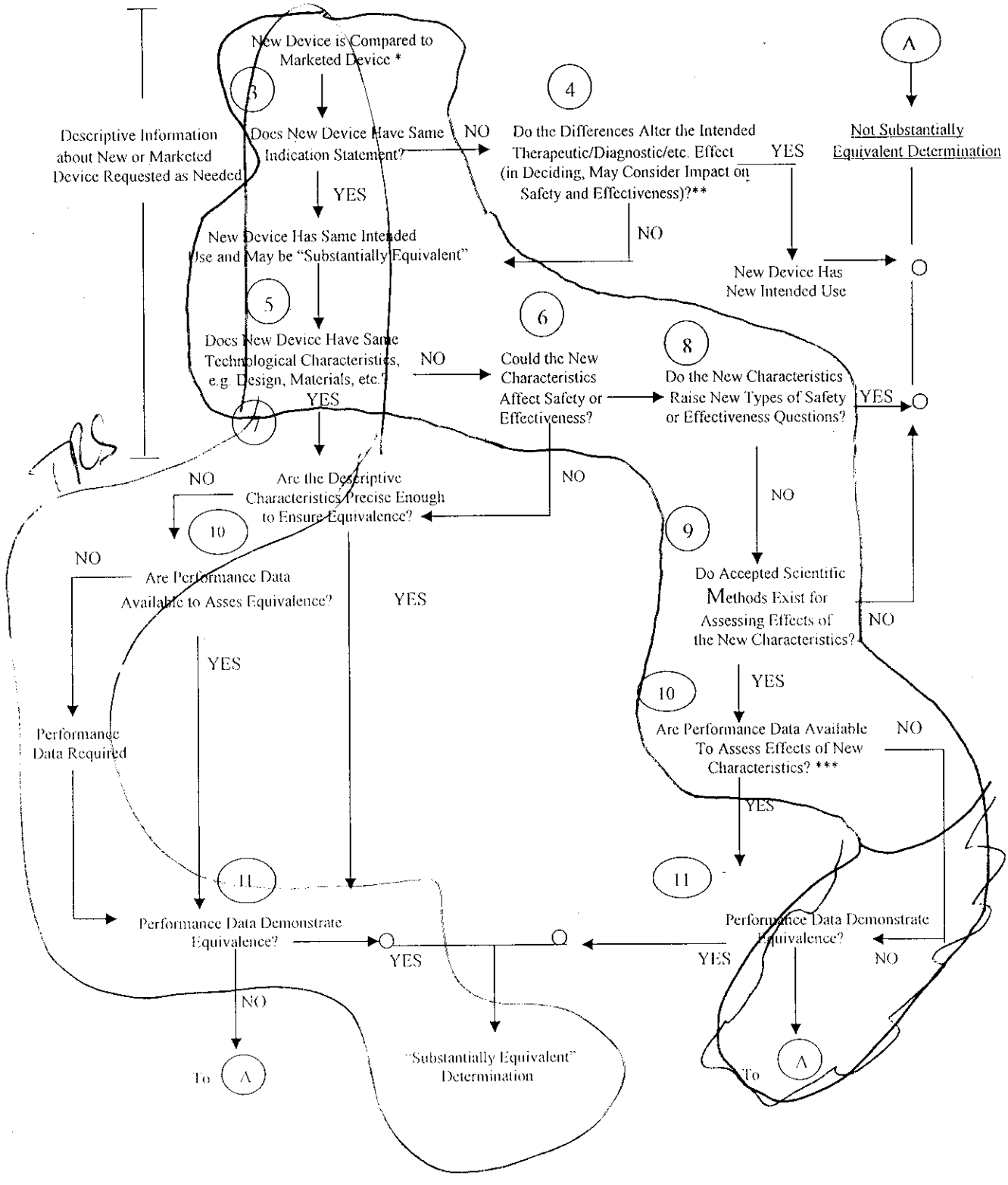
confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this email message in error, please email the sender immediately.

From: Peck, Jonathan H
Sent: Thursday, March 02, 2006 10:14 AM
To: Rosecrans, Heather S.; Melkerson, Mark N.; Stevens, Ted
Subject: Converting K060415 - Satellite Spinal System to a Traditional

(b) (5) [redacted]

Jonathan Peck
Mechanical Engineer
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch
9200 Corporate Boulevard, HFZ-410
Rockville, MD 20850
Phone: (301) 594-2036 Ext 122
Fax: (301) 827-4349
Email: jonathan.peck@fda.hhs.gov

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 02, 2006

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS, TN 38132
ATTN: RICHARD TREHARNE

510(k) Number: K060415
Product: MODIFICATION TO: SATELLITE SPINAL SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.
On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

CDs Received

		WITS Entry
☑	**1 CD** with entire submission	1CDT
☐ ___	**CDs** with entire submission	XCDT
☐	**1 CD** with each copy of submission	1CDPC
☐ ___	**CDs** with each copy of submission	XCDPC

☐	Check here if CDs were bound into volume(s)	XCDTB – XCDPCB
☐	Letter Stated CD(s) – NO CDs found in Packaging	LSCD – NO CDs
☐	True Electronic Submission (E-Copy) – w/proper cover letter stating so	ESUB 1/X – 1 or X

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Filename: C:\My Documents\Word\Forms\CDs Received in Mailroom

Medtronic
SOFAMOR DANEK

Regulatory Affairs Department

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
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fax 901.346.0738
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K060415/S1

September 28, 2006

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

ATTN: Jonathan Peck

Re: SATELLITE™ Spinal System - K060415

Dear Document Control Clerk:

On April 27, 2006 we received a request from the reviewer for additional information regarding the SATELLITE™ Spinal System, 510(k) submission (K060415) currently being reviewed by the agency. A teleconference was held on May 5, 2006, during which these issues were discussed. This letter contains our formal response to the agency's questions. The reviewer's questions are presented here in **bold** text while our responses follow in normal text. Along with one hard copy, an electronic copy is also included on a computer CD.

1. **You propose the addition of spheres manufactured from PEEK-OPTIMA LT1 to the Satellite Spinal system. This system has unique geometry as compared to other legally marketed fusion devices and you have not provided clinical information on the safety and effectiveness of this device as an adjunct to fusion. You have provided data from two bench tests, subsidence and push-out, which demonstrate that the PEEK Satellite™ Spinal System performs differently from the cobalt chrome predicate. The overall effect that this change in material could have on the performance of the Satellite™ Spinal System is not well understood and therefore cannot be fully described pre-clinically. Given our limited knowledge of how this device will perform in vivo, we believe clinical data are necessary to assess the affect this material change will have on the**

K 46
K72
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performance of the device. Therefore, please provide clinical data that demonstrate equivalence in terms of safety and effectiveness of the PEEK Satellite™ Spinal System for the indications sought. Please be advised that prior to initiating a clinical trial in the United States you must submit an investigational device exemption (IDE) application for review by the FDA.

We are confused by the FDA's question. The geometry of the subject device is identical to that of the predicate Satellite™ spheres, which in fact represent a legally marketed fusion device – See K051320. Therefore, the FDA has previously determined this device (from a geometry standpoint) to be safe. Regarding the PEEK material, the FDA has a long history of clearing PEEK versions of titanium fusion devices – both Class II and Class III – without clinical data. Class II devices include multiple clearances for the VERTE-STACK Spinal System, as well as PEEK rods used in conjunction with metal implants in the CD HORIZON® Spinal System, while Class III devices include the PEEK LT-CAGE™ PEEK Lumbar Tapered Fusion Device (P970015/Supplement 22 – Approved 09/10/03).

The LT-CAGE™ PEEK Lumbar Tapered Fusion Device was cleared for use from L2-S1 with bone graft via an anterior approach. The subject device is cleared for fusion procedures from L3-S1 with bone graft using an anterior approach. The VERTE-STACK™ Spinal System devices are to be used with bone graft and supplemental fixation from T1-L5 and can be implanted via either an anterior or a posterior approach. The purpose of all three systems is identical as all are intended to help promote fusion. Clinical data was never required to obtain clearance of any VERTE-STACK™ Spinal System device, the CD HORIZON® Spinal System, or the LT-CAGE™ PEEK Lumbar Tapered Fusion Device, all of which have more demanding and broader indications than the subject device.

Mechanical testing results including static axial compression, static shear compression and dynamic axial compression for the predicate device were provided to the FDA, however, it should be noted that in nearly all test methods the titanium version of the cage outperformed its PEEK counterpart. Despite this, the FDA had no qualms regarding the granting of clearance without clinical data.

Additionally, to better compare the subject SATELLITE™ device to its cobalt chrome counterpart, push-out and subsidence testing of the devices for both materials was performed. The purpose of the test was to determine that subsidence properties and push-out resistance of the 11mm PEEK implants and compare those to the 11mm diameter cobalt chrome devices. The in vitro subsidence testing performed was intended to mimic in vivo intervertebral subsidence that could occur while implant. Push-out testing was designed to represent the amount of lateral posterior force required to remove the implant from its in vivo vertebral body position.

The test results demonstrated that the subject PEEK implants outperformed its cobalt chrome counterpart in push-out resistance as the mean peak load for the PEEK implants was (b) (4) [redacted].

In subsidence testing the PEEK implants outperformed their cobalt chrome counterparts again with the mean peak load being (b) [redacted] for the subject implants compared to (b) (4) [redacted] for the predicate implants.

The complete test report (TR07-156) is provided in **Attachment 8**[1] of this response.

During an earlier teleconference with the reviewer it was noted that clinical data on the original predicate devices the Harmon Sphere and the Fernstrom Ball, were presented to the agency in the initial SATELLITE Spinal System submission. The reviewer requested that we resubmit the data for his review. The data is included in **Attachment 9** of this response with certain sections of significance highlighted.

2. **You have provided results of subsidence testing and push-out testing of your worst case PEEK device. The PEEK device exhibited a higher subsidence load and a higher push-out load than the predicate cobalt chrome device. We believe that these two tests do not fully pre-clinically address all of the potential risks that are associated with changing the device material from cobalt chrome to PEEK. The PEEK device could fail at low compression loads (static and fatigue) as compared to a legally marketed predicate device. In addition, the PEEK device could be subject to wear. Therefore, please:**

[1] Attachments 1-7 are found in the original submission.

a. **Provide results of static and dynamic compression testing of the worst case PEEK device. Please compare the results of these tests to a legally marketed predicate fusion device and provide a physiologic justification showing that the strength exhibited by the device in static compression and compression fatigue is adequate.**

Fatigue and Static Compression Testing of the subject SATELLITE™ device was conducted at the agency's request. All testing was performed in accordance with ASTM F2077, Test Methods for Intervertebral Body Fusion Devices, and the results are presented in TR07-103, found in **Attachment 10** of this submission.

In determining the worst case device, Medtronic selected the 11mm SATELLITE™ implant. At this time we are removing the 10mm implants from this submission. A revised implant list along with a revised engineering drawing noting the removal of the 10mm implant is provided in **Attachment 11** of this response.

The purpose of the test was to determine whether the subject device could withstand (b) (4) at a load of (b) (4). The 1500N load was chosen based upon the FDA document, Guidance for Industry and FDA Staff Spinal System 510(k)s" issued May 3, 2004. The test found that the subject implants were indeed able to withstand the (b) (4) load for the (b) (4) without fracture or failure.

b. **Provide results of wear testing on the worst case PEEK device. This test should mimic abrasion of the vertebral endplates against the device under worst case physiological loads and motions. If your device produces an excessive amount of wear, you may need to perform an animal study to demonstrate that the amount, size and morphology of the PEEK wear debris is acceptable. However, if the device produces minimal wear, you may be able to validate the results with the literature.**

All static compression and compression fatigue testing was performed in solution. The test devices were weighed prior to testing and then re-weighed at the conclusion of testing. The tests found that the implants actually gained weight during testing. Therefore, it was determined that no excessive amounts of wear debris were generated during testing.

The long-term mechanical integrity of PEEK spinal devices has also been demonstrated in independent published reports. An article published in the February 2006 issue of The European Spine Journal addressed this very question. In this study the authors noted that "the influence of a physiological environment on the mechanical stability of PEEK has not been reported. Furthermore, the suitability of the polymer for use in highly stressed spinal implants such as intervertebral cages has not been investigated." In order to study these devices the authors conducted compression tests to compare PEEK-OPTIMA devices to their titanium counterparts. The authors concluded that the "results verified the mechanical stability of the PEEK-OPTIMA polymer in a simulated physiological environment and over extended loading periods. Finite element analysis supported use of PEEK-OPTIMA for load-bearing intervertebral implants." A copy of the article is included in **Attachment 12** of this response.

3. **You state that the subject devices are manufactured from PEEK OPTIMA-LT1 and tantalum. However, you have not provided any specific information on the materials. Please provide the manufacturer of the materials and any standards to which the materials conform. Please identify a predicate device which utilizes these same materials in the spine. Then please describe if you have made any changes in manufacturing techniques used in the predicate that could potentially affect the biocompatibility or material properties of the device.**

The SATELLITE™ Spinal System PEEK devices are identical in materials to the previously cleared VERTE-STACK® Spinal System PEEK components as well as the CD HORIZON® Spinal System PEEK rods. All of these devices are manufactured from medical grade PEEK-OPTIMA LT1 described by ASTM Standard F2026. The Tantalum marker used for this product is made to the voluntary standard of ASTM F-560 and is identical to the Tantalum material used in the

aforementioned predicate devices. The VERTE-STACK® Spinal System was originally cleared by the FDA in K021791 (SE 08/23/02). A gamma-sterilized version of the product was subsequently cleared by the FDA in K023570 (SE 11/19/02). The CD HORIZON® PEEK rods were cleared in K050809 (SE 06/14/05). The SATELLITE™ Spinal System PEEK devices and the VERTE-STACK® Spinal System PEEK devices are manufactured by Medtronic Sofamor Danek Deggendorf located at WerfstraBe 17, Deggendorf, Germany. Additionally, the SATELLITE™ Spinal System PEEK devices and the VERTE-STACK® Spinal System PEEK devices are manufactured using identical processes. Therefore, nothing within the manufacturing process has been altered that could impact the biocompatibility or material properties of the subject device.

We believe that this fully addresses the FDA's request regarding this submission. If you have any further questions regarding this submission, please call me at (901) 396-3133. You may also email questions to me at christine.scifert@medtronic.com or to Lee Grant at lgrant@sofamordanek.com. Notification of clearance of this 510(k), or requests for further information may be sent to Medtronic Sofamor Danek by fax to me at (901) 346-9738.

Sincerely,

Christine Scifert

Christine Scifert
Group Director, Regulatory Affairs
Attachments

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Medtronic
SOFAMOR DANEK

Design Verification Test Report

TR07-156

(b) (4)

Push-out and Subsidence Testing of 11 mm Diameter PEEK and CoCr Satellite Implants

Testing Performed by (b) (4)

Prepared By: (b) (4)

Reviewed By:

Approved By:

45

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

VÄSTANBÄCKS LÄKARMOTTAGNING AB
Bergården, VÄSTANBÄCK
824 00 HUDIKSVALL
Tel. 0650/621 50
Postgiro 12 27 36 - 2

cppy

000046

To
Doctor J.A. Mayer, M.D.
Suite 14
2221 Keele Street
TORONTO, ONTARIO M 6 M 3 3 5
CANADA

Hudiksvall den 22 april 1973

Dear Dr. Mayer:

I am delighted to have informations from your experiences about steel ball. In may 1970 you wrote about 5 operated cases. I wonder if you have done any more operation with steel ball?

Before I answer your questions I will give you some informations about me and the steel ball method.

I am head of a general surgical clinic with 112 beds. During my education to become a general surgeon, with special education in traumatic surgery, I become a very careful instruction in neurosurgery durin three years (1946-1949) by professor Herbert Olivecrona and ass. professor Olof Sjöqvist in Stockholm. During this time I become very interested in discsurgery. The discsurgery has take a big part of my time as general surgeon, because there is no orthopaedic or neurological surgeon in my district. It is 75 miles (English) to the nearest orthopaedic center och 115 miles to neurosurgery center. I am also expert in traumatic surgery, which embrace orthopedic, neurologic, thoracic and abdominal surgery.

(b) (6)

[redacted]

(b) (6)

I still trust on this metho with steel ball and consider that is a good method by operation ruptured and fissured discs. But I have not excecute this operation after june 1970. It depends on that [redacted] (b) (6) [redacted].

During the summer 1970 I have done a careful after-examination of all patients who had been operated with steel ball. Totaly 195 cases, 207 operation and 267 inserted steel balls in the lumbar spine. In the cervical spine I have inserted steel ball by 12 cases.

About complications:	Number	%
Weakness or paresis (dorsiflexion of foot)	2	0,9
Steel ball prolaps or migration	2	0,7
Discitis or spondylitis	2	0,9
Spinal meningitis	1	0,4
Wound infection	2	0,9
Death of operation	0	0

Migration of steel ball occure always three weeks after operation and depends on too big steel ball. In cases with spondylitis or discitis there was no migration and this infection started always one week after operation. Migration of steel ball give no weakness or paresis and it was very easy to take away the steel ball from the spinal canal.

There is no erosion of vertebrae but the steel ball has sinking into teh vertebrae body, slight 74%, obvious 13% and totally 0,7% and in 12% the hight of the disc has not changed. This figures are from 164 steel balls observed during 5-7 years after operation.

About results I devide the cases in two groups namely:

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Goup I: Ruptured disc; to this group I relate herniated disc, complete or incomplete and bulging disc that in surgeon's opinion excert pressure on the nerve root.

Group II: Fissured disc; intact degenerated disc, degenerated disc with tear or chondrosis intervertebralis, fissuring of anjulus fibrosus. This cases have no nerve root compression. Only a fissure in the annular ligament, which give by discography pain of past history type. It is very important to know that discography also can give indifferent or unknown pain by injection.

Results:

Ruptured disc: Painless

Totally controlcases (50) no steel ball	
time of observation 5 years	30%
Steel ball cases (63)	
time of observation 1-3 years	84%
time of observation 5-8 years	66%
In back controlcases	40%
steel ball 1-3 years	88%
steel ball 5-8 years	73%
no sciatic pain controlcases	50%
steel ball 1-3 years	86%
steel ball 5-8 years	66%

Fissured disc: Painless

Totally controlcases (50) only evacuated disc	12%
time of observation 5 years	
steel ball cases (79)	
time of observation 1-3 years	54%
time of observation 5-8 years	35%
in back controlcases	12%
steel ball cases 1-3 years	60%
5-8 years	38%
no sciatic pain controlcases	20%
steel ball cases 1-3 years	62%
5-8 years	40%

It is very important to know the following about my cases:

1) All of them have free medical attention or treatment
2) All belongs to National Health Insurance
3) Most of the cases has also a private sickness insurance
4) Nonedy is private patient. I have not had extra income of this operation. I have a fixed salary every year from the hospital irre-

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5. Cases with fissured discs have had to choose between operation or disablement pension. It means that this cases are very difficult to treated. Before operation they have been treated conservative with physiotherapy, othopaedic corset and changing employment without no result.

My latest reprint is in Germany language but I hope You can read it or have it translated. Just now I prepare a more exstensive report in English and I should like to have it published in a big American journal. Perhaps it can be some difficulties to have it published owing to that Hirsch has throw dirt on my name.

Yours sincerely

Ulf Fernström,M.D.

Private adress:
Doctor Ulf Fernström
Sörgården, Västanbäck
824 00 Hudiksvall
Sweden

Adress to the hospital:
Doctor Ulf Fernström
Dept. of Surgery
Central Hospital
82401 Hudiksvall

Supplement: a reprint from my last report

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Best regards

FERNSTRÖM INTERVERTEBRAL DISC ARTHROPLASTY: A LONG-TERM EVALUATION

Alvin H. McKenzie, MD, MChOrth, FRCS(C)

ABSTRACT

The history of intervertebral disc arthroplasty is reviewed. The author describes his series of 103 patients who underwent Fernstrom intervertebral disc arthroplasties, most of them over 20 years ago. Patients were grouped according to original pathology: Group I (disc protrusions) and Group II (degenerative disc disease). Sixty-seven patients constituted a long term series reviewed between 10 and 20 years after surgery (average: 17 years). Selection of patients and surgical methods are described, and subsequent surgery is recorded and analyzed. Methods of assessment of results are detailed. Results of surgery in Group I patients and Group II patients in the long term series were graded excellent or good in 83% and 75%, respectively. Ninety-five percent of all patients returned to work: 77% to their preoperative level, and 18% to light or part time work. Return to work of 80% of the patients occurred by 5 months after surgery. Only 1 of 155 prosthesis required removal.

L'historique de l'arthroplastie du disque intervertébral est passée en revue. L'auteur présente une série de 103 patients ayant bénéficié d'une arthroplastie du disque intervertébral selon FERNSTROM, la plupart plus de 20 ans auparavant. Les patients ont été subdivisés selon la pathologie initiale: groupe 1 (protrusion discale) et groupe 2 (pathologie discale dégénérative). 67 patients ont étérevus avec un recul post-opératoire moyen de 10 à 20 ans (recul moyen: 17 ans). La sélection des patients et les méthodes chirurgicales sont décrites et les gestes chirurgicaux sont notés et analysés. La méthode d'évaluation des résultats est détaillée. Les résultats à long terme pour les groupes 1 et 2 ont été cotés excellents et bons dans respectivement 83% et 75% des cas; 95% de l'ensemble patients out repris le travail 77% au même niveau, 18% à temps partiel ou à un niveau moindre. Le délai de reprise du travail est de 5 mois dans 80% des cas. Seule 1 des 155 prothèses a dû être retirée.

Translated by Patricia Thoreux, MD

Der Autor gibt einen Ueberblick über Ersatz operationen an den Bandscheiben (Fernstrøm-Verfahren). Es wird über eine Serie von 103 Patienten berichtet, die meist vor über 20 Jahren einen intervertebralen Diskusersatz nach Fernstrøm erhalten hatten. Die Patienten wurden aufgrund der ursprünglichen Pathologie in zwei Gruppen aufgeteilt: Gruppe I (Diskus-Protrusion), Gruppe II (Diskus-Degeneration). 67 Patienten konnten zwischen 10 und 20 Jahren nach der Operation evaluiert werden (Durchschnitt: 17 Jahre). Die Auswahl der Patienten und die operative Technik wird beschrieben und analysiert. Beurteilungskri terien und Resultate werden detailliert erwähnt. Die Langzeitergebnisse ergaben sehr gute und gute Ergebnisse in 83% (Gruppe I), respektive 75% (Gruppe II). 95% aller Patienten konnten ihre Erwerbstätigkeit wieder aufnehmen, 77% in ihrem angestammten Beruf und 18% in einer leichteren Tätigkeit oder in Teilzeitarbeit. Die Wiederaufnahme der Arbeit erfolgte im Schnitt 5 Monate nach der Operation. Bisher musste nur eine von 155 Diskus-Prothesen entfernt werden.

Translated by Niklaus F. Friederich, MD

Se revisa la historia de la artroplastia del disco intervertebral. El autor describe su serie de 103 pacientes que sufrieron artroplastias de disco intervertebral de Fernstrom, la mayor parte de ellos hacía 20 años. Los pacientes fueron agrupados de acuerdo con la patología original: Grupo I (protrusiones discales) y Grupo II (enfermedad degenerativa discal). Sesenta y siete pacientes constituyeron una serie a largo plazo, revisados entre 10-20 años despus de la intervención (media: 17 años). Se describe la selección de los pacientes y las técnicas quirúrgicas, y la cirugía posterior es

[redacted] *Clinical Professor, Department of Surgery, University of Alberta (Royal Alexandra Hospital), Edmonton, Alberta, Canada.*

Reprint requests: A.H. McKenzie, MD, MChOrth, FRCS(C), 303, 10106-111 Ave, Edmonton, Alberta T5G 0B4, Canada.

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registrada y analizada. Se detallan los métodos de valoración de resultados. Los resultados de la cirugía en pacientes del Grupo I y del Grupo II en la serie a largo plazo, fueron calificados como excelentes o buenos en un 83% y 75% respectivamente. El 80% de los pacientes volvieron al trabajo 5 meses después de la cirugía. Solo I de cada 155 pacientes necesitaron extracción.

Translated by Antonio Saez, MD

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Viene riportata la storia della protesi del disco intervertebrale. L'autore ziporta uno serie di 103 pazienti che sono stati operati con protesi di Fernstrom del disco intervertebrale, la maggioranza di questi operati da oltre 20 anni. I pazienti sono stati raggruppati secondo la patologia: Gruppo I (protrusione discale) e Gruppo II (malattia degenerativa del disco). 67 pazienti formano un gruppo costituito da pazienti operati da 10-20 anni prima (media 17 anni). Sono descritti vi criteri di selezione dei pazienti e la metodiche chirurgiche. Tutti questi dati sono inoltre registrati ed analizzati. I metodi di valutazione dei risultati sono discussi in dettaglio. I risultati della chirurgia nel Gruppo I e nel Gruppo II sono stati rispettivamente eccellenti e buoni nel 83% e nel 75% dei casi. Il 95% dei pazienti sono ritornati al lavoro: 77% al loro lavoro prima dell'intervento, 18% ad un lavoro più leggero o ad uno part-time. Il ritorno al lavoro è avvenuto entro 5 mesi nell 80% dei pazienti. Solo I protesi su 155 è stata rimossa.

Translated by Pier Giorgio Marchetti, MD

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椎間板関節形成術の歴史を概観する。大部分は２０年前に行われたフェルンストローム椎間板関節形成術の１０３患者についてのシリーズを報告する。患者は原疾患によってグループ化した：グループＩ（椎間板突出）とグループII（椎間板変性）の２群である。６７患者は長期のシリーズで、経過観察期間は術後１０年から２０年（平均：１７年）であった。患者の選択と手術方法の選択を述べ、その後に行われた手術を記録し、分析する。手術結果の評価方法について詳細に述べる。グループＩとグループIIの患者の長期観察での手術結果で、優または良と評価したのは、それぞれ８３％と７５％であった。全症例の９５％は仕事に復帰した。７７％は手術前のレベルに、１８％は軽作業またはパートタイムの仕事に復帰した。患者の８０％では、術後５ヵ月までに仕事に復帰した。１５５プロステーシスのうち１個のみが除去を必要とした。

Translated by Katsuji Shimizu, MD

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Methods of preserving or restoring stability or function at the intervertebral level have been debated and attempted for many years. Interbody Vitallium spheres were used successfully as early as 1957 by Paul Harmon in place of a fibular cylinder as an aid to stabilizing the intervertebral disc space and augmenting interbody fusion.[1] In 1964, intercorporal steel balls were used as a form of arthroplasty of the lumbar and cervical spine by Ulf Fernström of Uddevalla, Sweden.[2] Subsequently, Hjalmar Reitz[3] carried out Fernström procedures and also attempted to replace the intervertebral disc in the cervical vertebrae with steel hemispheres and Silastic prostheses. More recently, silicon Dacron implants have been tried on animal models with difficulty,[4] and other elaborate models have been suggested.[5] John Kostuik recently has described a spring loaded, double-plated hinge that he has been using as an intervertebral disc substitute,[6] and Buttner-Janz et al have developed their SB Charity endoprosthesis.[7] Some of these prostheses require anterior approaches to the spine and may have morbidity factors common to those of anterior spinal fusion.

Armstrong[8] suggested that the plane of intervertebral movement could be described approximately by the movement of contiguous vertebrae over a small ball located in the nucleus pulposus recess. He and Roaf[9] observed that compressive forces on the vertebrae may cause the nucleus pulposus to act like an incompressible sphere and, in fact, could cause the vertebral end plates to collapse, with the nucleus pulposus prolapsing into the vertebral bodies while the nucleus and annulus remained intact.

Fernström anticipated that postdiscectomy interposition of properly sized steel balls in the nuclear recesses between the vertebral bodies would maintain a semblance of the normal intervertebral relationship and motion while preserving stability through ligamentous tension on the annulus. Relative normalcy at the operative level seemed likely to reduce adverse effects on adjacent vertebral levels. Fernström

Fig 1A: Lateral view lumbar spine preoperatively (patient 32).

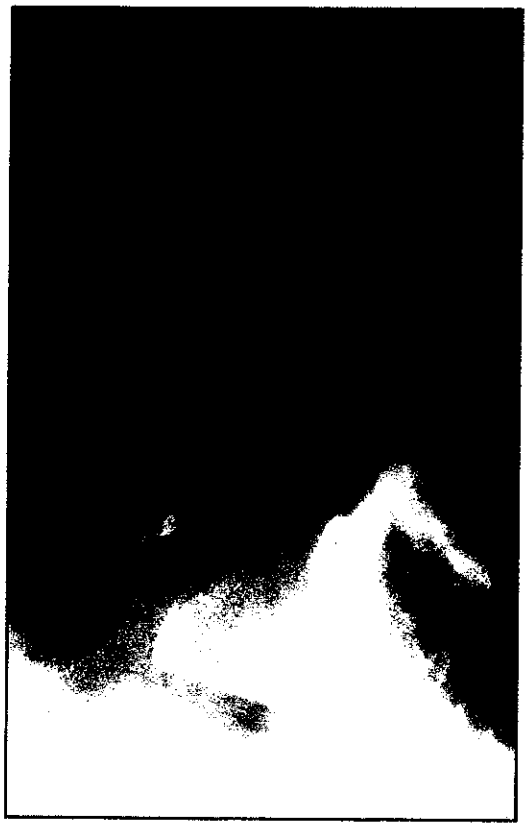


Fig 1B: Same patient, 1 year postoperatively.

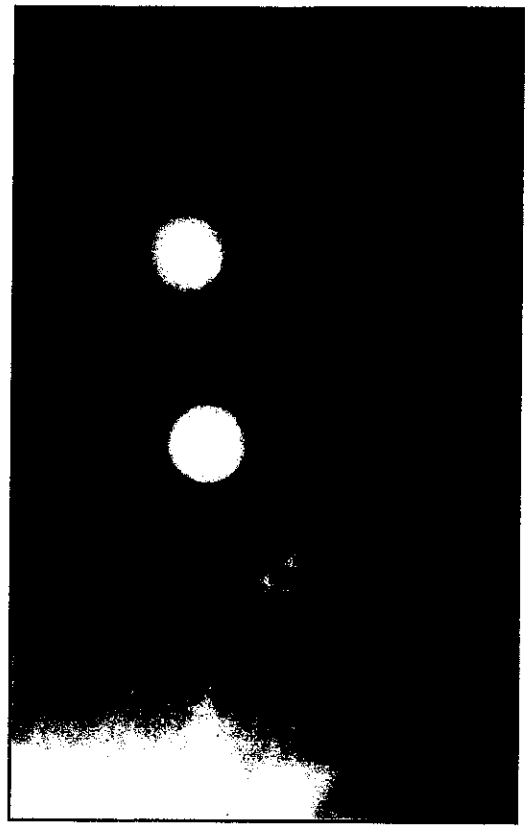
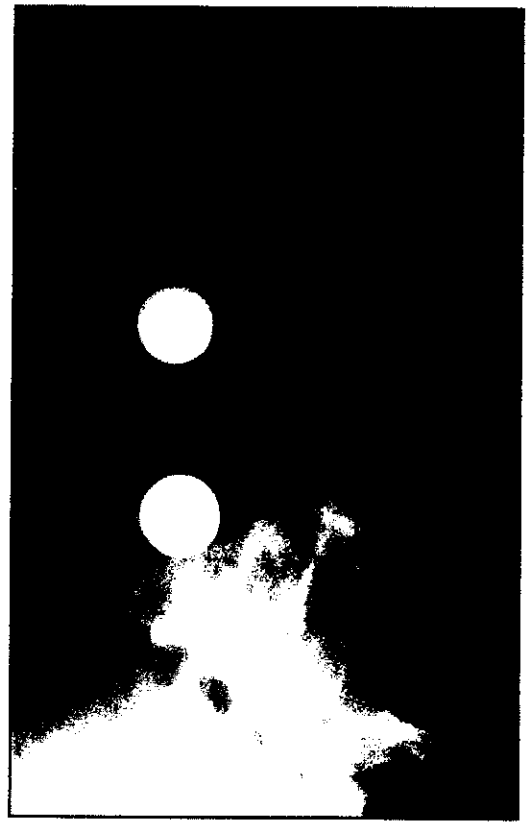


Fig 1C: Same patient, 17 years postoperatively.



anticipated that there probably would be some subsidence of the steel balls into the vertebral bodies in the course of time, but he believed that this process would be slow enough for the ligaments and joints to adapt. In the event of facet joint problems developing and the need for fusion occurring, an interposed metal sphere would not hinder the fusion.

Twenty-five years ago, surgical solutions for spinal disorders consisted of discectomy, fusion, or a combination of the two and were frequently unsatisfactory. Often, nonsurgical solutions were equally disappointing. Whether the causes of failure were related to patient selection, erroneous or incomplete diagnoses, or operative selection, the need existed for better solutions. Diagnostic methods were pursued to the limit of available technology. Patient selection was based on a somewhat vague "wariness index," which varied from surgeon to surgeon depending on his or her training and experience. Beyond that, the patient selection for surgery depended primarily on the results of history, physical examination, plain radiographic films, myelography, and occasionally discography. Failures of discectomy seemed related to recurrent disc protrusions, protrusions at new levels, instability, fibrosis of nerve roots and cauda equina, and facet arthritis. Spinal stenosis as a diagnosis rarely was accepted by the orthopædic community.

The author's experience with steel ball arthro-

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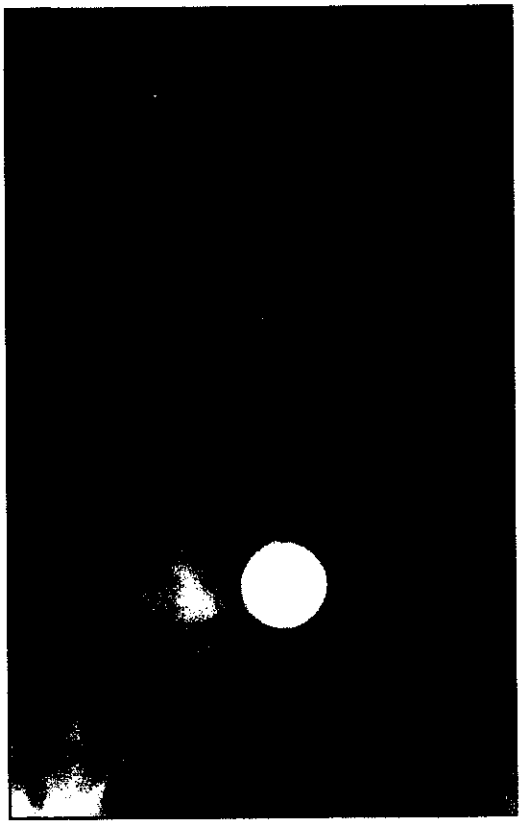
Table 1

PATIENT GROUPS				
	Total Series (103 patients)		Long-Term Series (69 patients)	
Category	No.	%	No.	%
Group I (disc protrusions)	44	43%	29	42%
Group II (degenerative disc disease)	59	57%	40	58%

Fig 2A: AP view, double nuclear recess at L4-L5 (arrows) (Patient 63).

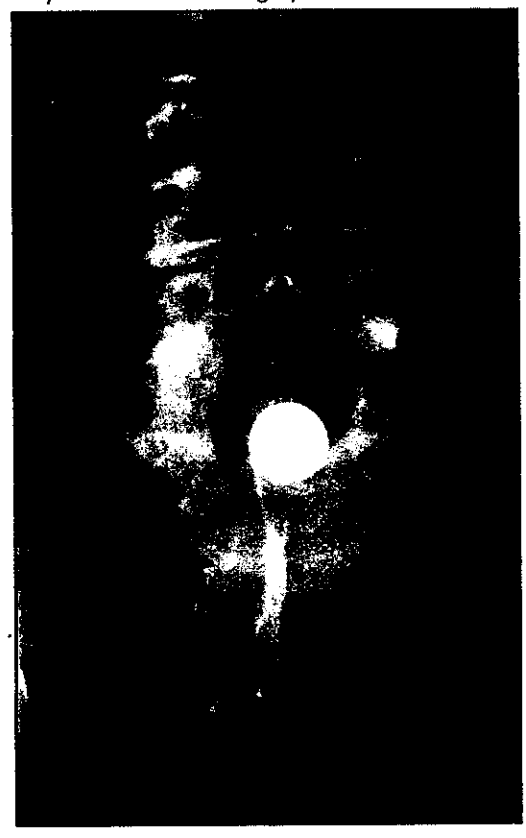


plasty began with his attendance at Ulf Fernstrom's clinic in Sweden in 1969 to see his patients and participate in some of the operative procedures. The first report of my own series of Fernström procedures, with commentary by Paul Harmon and Ulf Fernström, took place at the 1971 Canadian Orthopædic Association meeting in Jasper, Alberta.[10] This report reviewed the early results of the procedure in 40 patients, half of whom had acute disc protrusions, and half of whom had disabling degenerative disc disease. Excellent and good results seemed to be developing in 85% of the surgically treated patients, with poor results in 6%.

MATERIALS AND METHODS

Patient Population and Classification. The study included 103 patients; two patients lost to follow up early in the postoperative period were

Fig 2B: AP view, single nuclear recess (patient 9, 19 years after initial surgery).



deleted from the study. Sixty-seven of these patients were observed on a long-term basis (range, 10 to 20 years; average, 17 years) through questionnaires, interviews, physical examination, radiographs (Fig 1A–C) and, in some cases, radionuclide bone imaging. Bone imaging obtained in 10 randomly selected long-term follow up patients did not show any reaction about the prostheses, and the results are not otherwise tabulated. The 67 patients who underwent in-depth review hereafter will be referred to as the "long-term series." The total assessed patient population of 103 patients hereafter will be referred to as the "total series."

Patients were subclassified into two main groups (Table 1):

- Group I: Patients whose primary reason for surgery was one or more intervertebral disc protrusion(s), who had not responded to conservative treatment, and who had sciatica, appropriate neurological deficit, and positive correlation with myelography. These constituted 44 of the 103 in the total series (43%) and 29 of the 69 in the long-term series (42%).
- Group II: Patients who had not responded to conservative treatment, who suffered primarily from degenerative disc disease or postdis-

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Table 2

FERNSTROM PROCEDURES

	Group I						Group II					
	Initial No. Fernstrom Procedures		New-Level Fernstrom Procedures		Final No. Fernstrom Procedures		Initial No. Fernstrom Procedures		New-Level Fernstrom Procedures		Final No. Fernstrom Procedures	
	TS*	LTS†	TS	LTS	TS	LTS	TS	LTS	TS	LTS	TS	LTS
One-Level Fernstrom Procedure												
L3-L4	1		1	1	1		4	2	1	1	3	1
L4-L5	19	15			16	13	9	6	1	1	7	5
L5-S1	19	10	2	1	19	10	10	5	1		9	4
Other						2	1			2	1	
Two-Level Fernstrom Procedure												
L3-L5	3	2			4	3	4	3			5	4
L4-S1	2	2			4	3	24	17	1	1	25	18
Other						3	3	1	1	3	2	
Three-Level Fernstrom Procedure												
L3-S1							3	4			4	4
Other												
Four-Level Fernstrom Procedure												
L2-S1											1	1
Total Patients 103/69	44	29	3	2	44	29	59	40	5	4	59	40
Total Levels 155/110	49	33	3	2	52	35	96	69	7	6	103	75

* = *Total series*
† = *Long-term series*

cectomy states with associated facet arthritis and/or instability, and who were candidates for spinal fusion. Most had disc ruptures with positive symptomatic discograms. These constituted 59 of the 103 in the total series (57%) and 40 of the 69 in the long-term series (58%).

Patient Selection, Surgical Method, and Follow-Up Care. Aside from the clinical criteria mentioned in the patient groups, certain anatomical requirements evolved as experience was gained with the procedure. Moderately advanced lumbar spondylosis with facet arthritis usually precluded a favorable outcome for the Fernström procedure. Radiographic evidence of a double as opposed to a single nuclear recess (Fig 2 A-B) was an unfavorable feature. Single recesses allowed for proper centering of the prosthesis, whereas double recesses predisposed to postoperative scoliosis. Double recesses could be converted to single ones by curettage, but this would be accompanied by infraction of the cartilaginous end plate of the vertebral bodies and could lead to migration of the prosthesis into the bone. The width and volume of the spinal canal could be estimated from the review of radiographs, but the final decision about the adequacy of the spinal canal for safe introduction of the prosthesis was made at the time of surgery. In addition to adequate canal volume to accommodate the cauda equina and the steel ball, the associated nerve roots had to be mobile enough for their safe retraction and protection. Severe intervertebral disc narrowing not associated with marked facet joint changes was not a contraindication to Fernström arthroplasty if the intervertebral space could be restored by the use of progressively larger Fernström sizers. In fact, disc space distraction often seemed to overcome instability associated with disc space collapse. The operative procedure required standard instruments for lumbar discectomy plus a large Cloward spreader used between the spinous processes to increase the posterior intervertebral disc opening. These instruments were augmented by a set of Fernström graduated disc space sizers, a set of graduated hem-

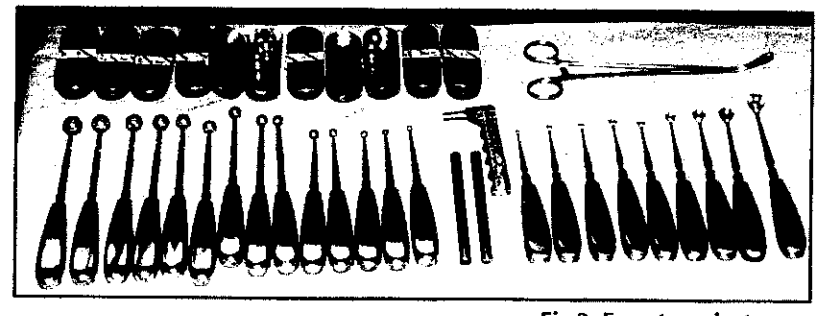

Fig 3: Fernstrom instruments, graduated disc space curettes (lower right); punches (lower center); sizers (lower left); selection of acid-resistant coated steel balls (upper left); ring forceps (upper right); measuring caliper (center).

Table 3

SUBSEQUENT SURGERY AT THE SAME LEVEL(S) AS FERNSTROM ARTHROPLASTIES

Procedure and Group (I or II)	Same-Level Discectomy	Discectomy and Prosthesis Exchanged	Same-Level Decompression	Same-Level Decompression and Fusion	Same-Level Fusion	Prosthesis Removed and Fusion	Total Same-Level Secondary Surgery
One-Level Fernstrom Procedure							
L3-L4						1 (I)*	
L4-L5	1 (I)	1 (I)					
L5-S1			1 (I)		1 (II)†		
Other							
Two-Level Fernstrom Procedure							
L3-L5	1 (I)		2 (I, II)		1 (II)		
L4-S1			3 (II, II, II)	2 (II, II)	1 (II)		
Other			1 (II)				
Three-Level Fernstrom Procedure							
L3-S1							
Other							
Four-Level Fernstrom Procedure							
L2-S1				1 (II)			
Total patients 103	2	1	7	3	3	1	17
Total Levels 155	2	1	13	8	6	1	31

(I) or (II) denotes Group I or Group II
** = Postoperative discitis*
† = Spondylolisthesis

ispherical curettes, a prosthesis punch, and a selection of acid-resistant coated steel balls ranging in size from 3/8" to 3/4" in diameter (Fig 3).

Although Fernström did most of his steel ball arthroplasties while the patient was under local anesthesia, this series of procedures was performed with the use of general anesthesia. The patients were positioned prone over lateral torso bolsters on an operating table with lumbosacral flexion/extension ability. The operated level was approached through a midline incision, bisecting the posterior longitudinal ligament and interspinous ligaments, with bilateral reflection of all soft tissues. Somewhat more than half of the ligamentum flavum on the side of maximum pathology was removed, and exposure of the spinal canal was increased by a moderate-sized laminotomy superiorly, inferiorly, and laterally. Pathology within the spinal canal was dealt with and nerve roots were mobilized to enable their safe retraction. Interspinous separation usually was enhanced with a Cloward spreader, which was opened once the nerve roots were free. The intervertebral disc was fenestrated adequately to permit thorough removal of degenerate disc material with rongeurs and irrigation. Graduated curettage with Fernström curettes was then carefully carried out, attempting to preserve end-plate cartilage and especially avoiding removal of any cortical bone in the nucleus pulposus recesses. When a suitable recess had been developed, Fernström sizers were then used to determine the size of steel ball that would fit snugly in position and feel stable without over-distraction of the disc space. After determination of the size of the recess and with the nerve root safely preserved medially, the steel ball of predetermined size would be positioned over the disc fenestration and tapped into the disc space and into the nuclear recess by means of the Fernström punch. Almost invariably, the prosthesis would pop firmly into place and restore stability to the surgically treated level. Only on one or two occasions did the steel ball require recovery with smooth faced lion-jaw forceps for resizing and reseating. When the steel ball was positioned, the table would be extended and the interspinous interval allowed to return to normal. Interspinous ligaments would then be reapproximated with figure eight sutures. Closure would be completed in the usual fashion.

Postoperative mobilizing and rehabilitation was carried out as it would be for a patient who had undergone routine discectomy. Walking

Fig 4A: Lumbosacral Fernstrom arthroplasty for disc protrusion, asymptomatic for 17 years.

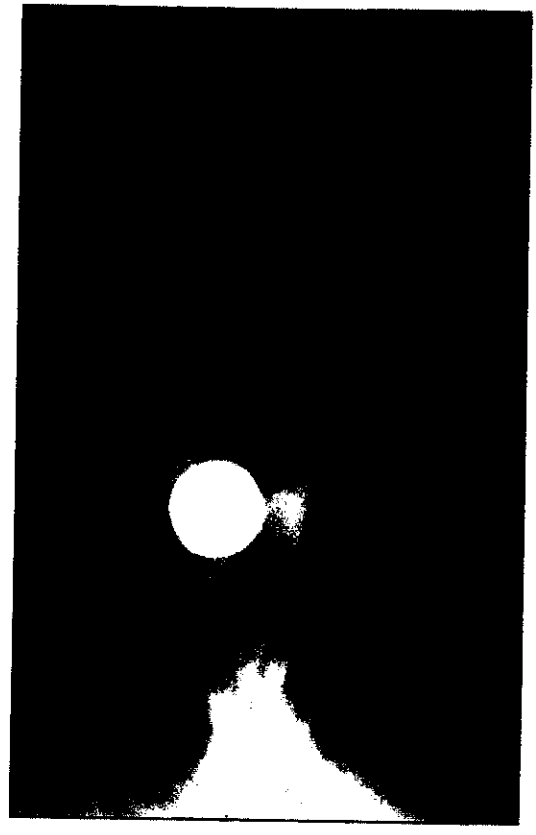

Fig 4B: Patient reappeared in 1988 with symptoms of L5 stenosis, which responded to decompression (patient 63).

was encouraged, but sitting in a low seat was discouraged for the first 3 weeks. Patients usually were discharged from the hospital at 3 to 5 days postoperatively, and follow-up physiotherapy activities were designed to restore normal posture and mobility, and return the patient to light work by 6 to 8 weeks. Unrestricted activity was permitted at 3 months postoperatively.

Analysis of Surgical Procedures. The total series of 103 patients who underwent discectomy and intervertebral steel ball arthroplasty at 155 levels were reviewed (Table 2). Ninety-five of the 103 patients had one-stage surgery at 145 levels, and 8 had a second-stage arthroplasty procedure to extend the surgical levels by 10.

After the Fernström arthroplasties, additional procedures were carried out at the same level as the Fernström arthroplasties in 17 patients (Table 3). One prosthesis was removed and a fusion done for discitis in a Group I patient. One patient with an undersized prosthesis who had a same-level disc protrusion with shifting of the prosthesis underwent discectomy with exchange of the prosthesis. Two other patients from Group I were reexplored, and foraminal disc material was recovered. Same-level decompressions were performed in 2 Group I patients and 8 Group II patients (Fig 4 A-B). Six Group II patients underwent fusion: 5 for facet arthritis and 1 for spondylolisthesis.

Additional procedures also were done at new levels of the spine in 11 patients (Table 4): 3 new-level discectomies (2 from Group I and 1 from Group II), 6 new-level decompressions (3 from Group I and 3 from Group II), and 2 new-level fusions (both from Group II, 1 with facet arthritis and 1 with spondylolisthesis).

Remotely related additional surgery consisted of a sciatic neurolysis for posttraumatic sciatic nerve fibrosis, a release of lateral femoral cutaneous nerve for meralgia paresthetica, suboccipital neurolysis carried out elsewhere, and a coccygectomy.

Spontaneous fusions occurred in 1 Group I patient and 2 Group II patients (Fig 5 A-B).

Results

Patients underwent a preoperative, early postoperative, and late postoperative assessment primarily using a disability or outcome grading system similar to one recently suggested by Greenough and Fraser (Table 5).[11] As in the Greenough and Fraser method, a set standard had to be achieved in all six categories, except that a drop by one grade in one factor was permitted. Patients also were assessed physically for posture, ambulatory ability, range of motion, muscle bulk and strength, sensory test-

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Table 4

SUBSEQUENT SURGERY ADJACENT TO AND REMOTE FROM FERNSTROM ARTHROPLASTIES

Procedure and Group (I or II)	New-Level Discectomy	New-Level Decompression	New-Level Decompression and Fusion	New-Level Fusion	Total New-Level Spinal Surgery	Spontaneous Fusion	Other Surgery
One-Level Fernstrom Procedure							
L3-L4		1 (I)		1 (I)	2		
L4-L5	1 (II)	3 (I, I, II)			4	1 (I)	
L5-S1	1 (I)	1 (II)			2		1*
Other							
Two-Level Fernstrom Procedure							
L3-L5				1 (II)†	1		
L4-S1						2 (II, II)	1*
Other	1 (I)	1 (I)			2		1*
Three-Level Fernstrom Procedure							
L3-S1							1*
Other							
Four-Level Fernstrom Procedure							
L2-S1							
Total Patients 103	3	6	0	2	11	3	4
Total Levels 155	3	10	0	2	15	4	NA

(I) or (II) denotes Group I or Group II
** = sciatic neurolysis, meralgia paresthetica release, suboccipital neurolysis, coccygectomy*
† = spondylolisthesis

Fig 5: Spontaneous fusion, asymptomatic 17 years after original procedure (patient 11).

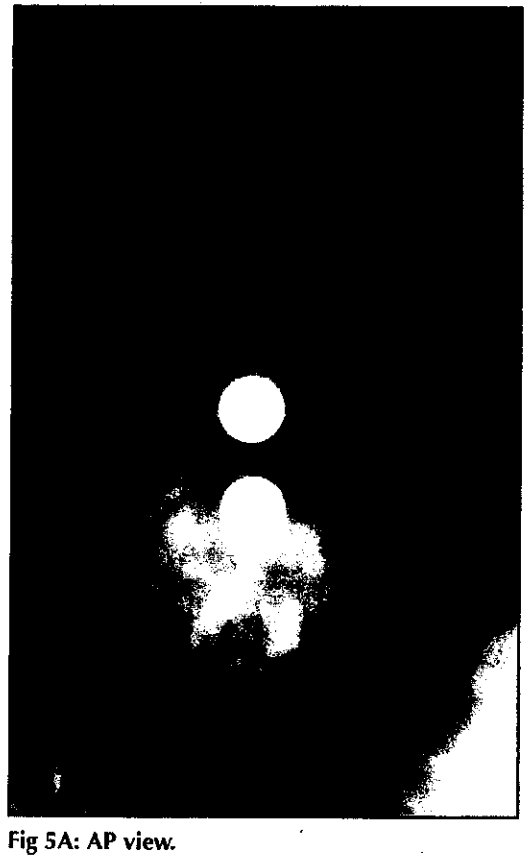

Fig 5A: AP view.

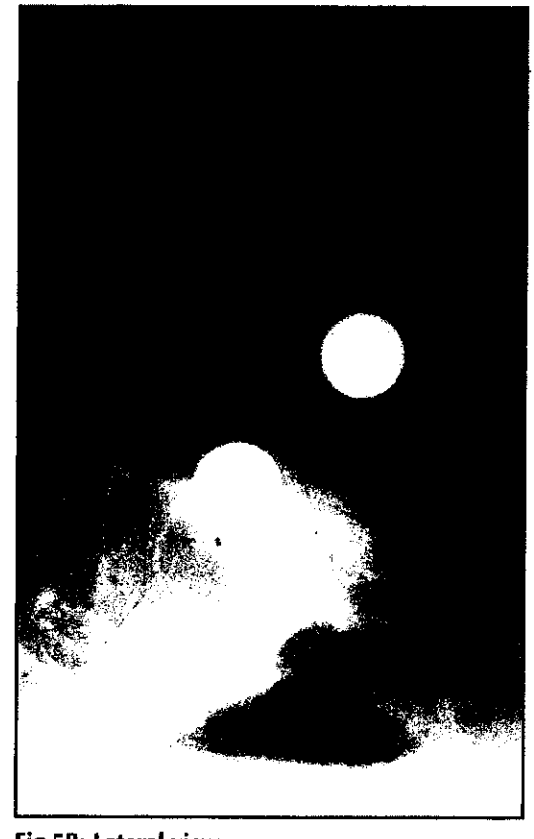

Fig 5B: Lateral view.

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Table 5

DISABILITY AND OUTCOME ASSESSMENT

	Employment	Pain Visual Analogue Scale (0-10)	Sports and/or Recreational Activity	Rest Required (decreased endurance)	Sexual Activity	Mental Outlook	Overall Result
Excellent (E)	Full-time same (S)	0-2	Original	None	Original	Original	E
Good (G)	Full-time light (L)	3-4	Most of original	Slight	Mildly affected	Slightly affected	G
Fair (F)	Part-time (P)	5-6	Only a little	Moderate	Moderately affected	Mildly depressed	F
Poor (P)	Unemployed (O)	7-10	None	More than ½ day	Absent	Severely depressed	P

Grading dependent on achieving a set standard in all six categories, permitting a maximum of one grading one level below predominant level.

Table 5A

PHYSICAL ASSESSMENT

	Posture	Ambulatory Ability	Spinal Range of Motion	Muscle Bulk and Strength	Sensory Testing	Stress Testing	Reflexes	Overall Results
Excellent	Normal	Normal gait	Normal	Normal for age and structure	Normal	Asymptomatic	Normal	E
Good	Minor list or alteration of lordosis	Minor occasional alteration of gait	Slight restriction, one direction	Minor descrepancy	Minor subjective alteration	Minor positive test at extremes	Slight discrepancy	G
Fair	Moderate list or alteration of lordosis	Persistent minor alteration of gait	Moderate restriction, more than one direction	Measurable wasting and weakness	Partial segmental numbness	Positive SLR greater than 60°	Moderate alteration	F
Poor	Gross alteration of posture	Significant or moderate alteration of gait	Significant restriction, more than two directions	Moderate segmental wasting and weakness	Complete loss, one or more segments	SLR less than 60°; positive Lasegue and/or Kernig's	Unilateral absent reflex with reinforcement	P

Grading dependent upon achieving a set standard in all seven categories permitting a maximum of two gradings, one level below predominant level or one grading two levels below predominant level.

ing, stress testing, and reflexes (Table 5A). These results were used only to confirm the disability and outcome assessment and were given less weight than the disability and outcome assessment. The radiological assessment (Table 5B) did not affect the final grading but is enclosed for interest. It measures the relative changes in the disc from normal and follows a four-level grading system based on disc height, condition of facet joints, and presence or absence of stenosis (Figs 6–9). The overall assessment of 103 patients in the total series and 67 patients in the long-term series is summarized in Table 6.

As expected, the Group I patients fared better than the Group II patients, ie, 83% excellent or good in Group I versus 75% excellent or good in Group II in the long-term series, and 75% excellent or good in Group I versus 70% excellent or good in Group II in the total series. In both series, most of the fair results were in Group II patients, and most of the poor results were in Group I patients, ie, 7% versus 0 to 3%.

The results of assessment of the total series of

Table 5B

RADIOLOGICAL ASSESSMENT

1a to 4a	1 to 4 disc levels with normal disc height and no change in facet joints (Fig 6)
1b to 4b	1 to 4 disc levels with minor changes in disc height and minor facet joint changes (Fig 7A & B)
1c to 4c	1 to 4 disc levels with moderate loss of disc height with facet sclerosis and spurring (Fig 8A & B)
1d to 4d	1 to 4 disc levels with marked loss of disc height with stenosis or fusion (Fig 9)

Table 6

ASSESSMENT OF RESULTS

	Excellent	Good	Fair	Poor	Total
Total Series (103 patients assessed)					
Group I	20 (45%)	13 (30%)	7 (16%)	4 (9%)	44 (100%)
Group II	14 (24%)	27 (46%)	16 (27%)	2 (3%)	59 (100%)
Total	34 (33%)	40 (39%)	23 (22%)	6 (6%)	103 (100%)
Long-Term Series (69 patients assessed)					
Group I	14 (48%)	10 (35%)	3 (10%)	2 (7%)	29 (100%)
Group II	11 (28%)	19 (47%)	9 (23%)	1 (2%)	40 (100%)
Total	5 (36%)	29 (42%)	12 (18%)	3 (4%)	69 (100%)

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Table 7

EVENTUAL WORK STATUS

	Same Employment (S)	Lighter Full-time Work (L)	Part-time Work (P)	Unemployed (O)	Total
Group I	34 (77%)	8 (18%)	0 (0%)	2 (5%)	44
Group II	45 (76%)	10 (17%)	1 (2%)	3 (5%)	59
Total	79 (77%)	18 (17%)	1 (1%)	5 (5%)	103

Table 7a

TIME TO RETURN TO WORK: GROUP I

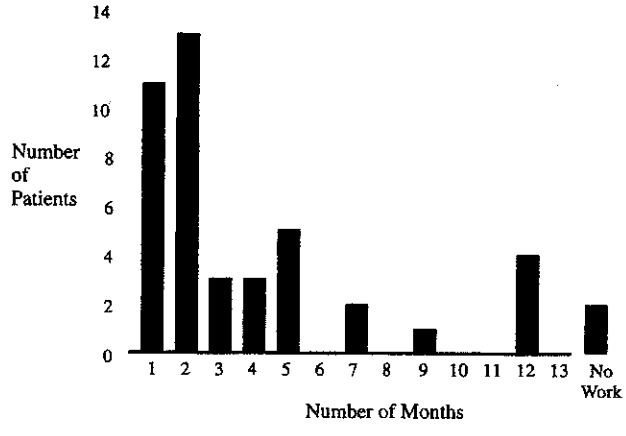
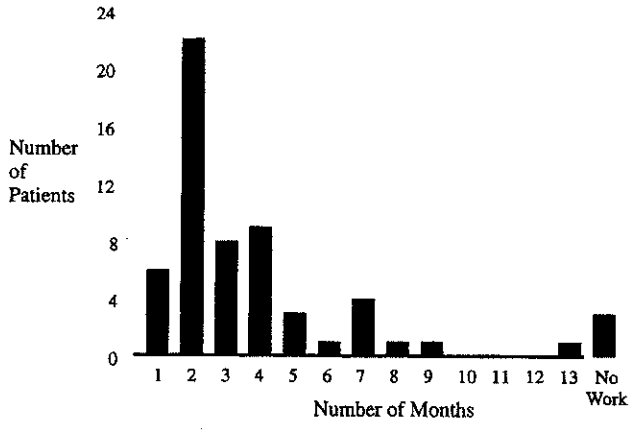


Table 7b

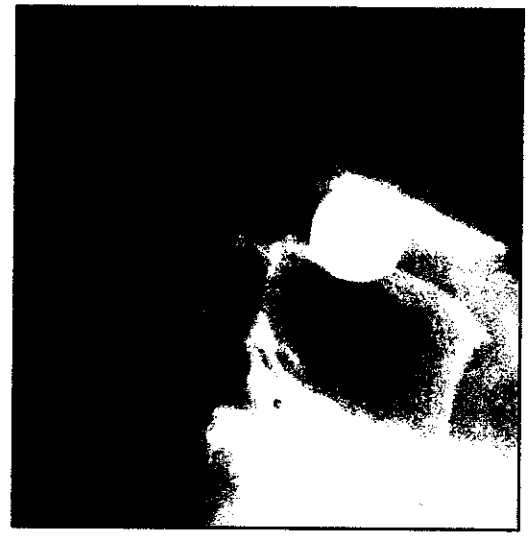
TIME TO RETURN TO WORK: GROUP II



103 patients are reasonably similar to those of the long-term series of 67 patients. Because of inexact knowledge of the outcome of patients reviewed less than 10 years after surgery, there was a tendency to downgrade their projected results.

The eventual work status of the total series also was reviewed (Table 7). Ninety-five percent of all patients returned to work: 77% of the patients at their previous level of employment, 18% at light or part-time work, and only 5% did not resume work. Time of return to work is illustrated in Tables 7A and 7B. Eighty percent of the patients were back at work by 5 months postoperatively.

Fig 6: Lateral view, 20 years postoperatively [Grade 2a] (patient 42).



DISCUSSION

Aspects of the series that probably deserve further analysis are extension of the Fernström levels to 10 new levels in 8 patients (8%); subsequent same-level surgery in 17 patients (16%); subsequent adjacent-level spinal surgery in 11 patients (10%); discitis in 4 patients (4%); and the occurrence of fair and poor results in approximately 25% of the patient population.

The eight patients who underwent new-level Fernström procedures were found to have residual problems that extension of the procedure did not always solve. Many of the new or residual problems that occurred were related to spinal stenosis, a condition whose existence and ramifications were to slowly dawn on the community of spinal surgeons after most of the Fernström prostheses had already been in place. As well as the limited knowledge of the day, the deficiencies of the diagnostic tools restricted interpretation of the extent and nature of preoperative spinal pathology ("You can't see what you don't know or know what you can't see").

It may be that in a few instances, steel balls of slightly greater than optimal size were used, so that disc weaknesses at adjacent levels became manifest. Same-level surgery for disc fragments is not peculiar to this procedure but may reflect on the surgeon. Patients with spondylolisthesis were not helped by the procedure, nor were

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Fig 7: Flexion-extension lateral views, 18 years postoperatively [Grade 1b] (patient 21).

Fig 8: Three-level procedure: outcome excellent but with moderate disc space narrowing and early facet arthritis [Grade 3c] (patient 89).

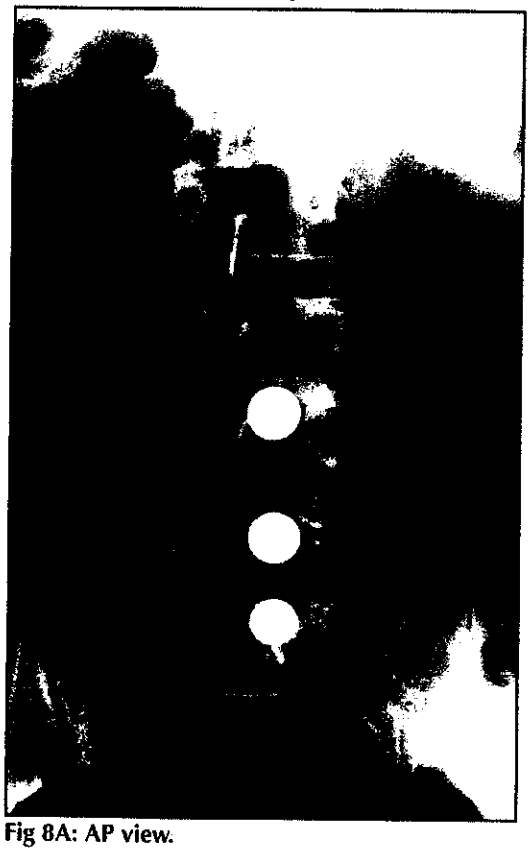

Fig 8A: AP view.

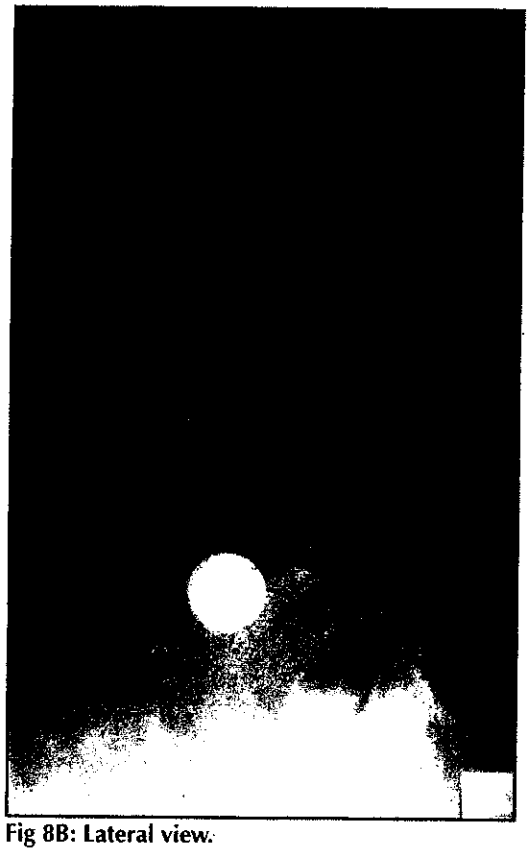

Fig 8B: Lateral view.

some of those with facet arthritis. In consequence, eight patients required spinal fusion. It is perhaps significant that, of the 59 Group II patients who were initially totally disabled and were candidates for spinal fusion, only 5 eventually underwent spinal fusion and the other 3 underwent decompression and fusion. Aside from the 3 who underwent decompression and fusion, 13 other patients ultimately underwent decompression procedures, 7 at the level of their Fernström procedure and 6 at adjacent levels. Thirty-three of the 44 Group I patients and 42 of the 59 Group II patients underwent Fernström procedures only.

Four of the 105 patients developed postoperative discitis at one level of the spine. All were

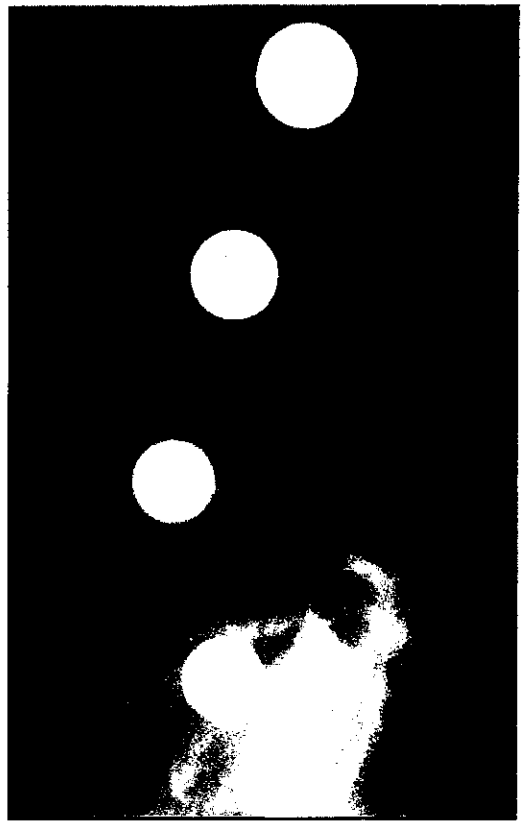

Fig 9: Four levels solidly fused [Grade 4d] (patient 2).

treated with intravenous antibiotic therapy and bed rest, followed by ambulation in a torso jacket. One patient developed a spontaneous interbody fusion at the affected level, one required anterior decompression with removal of the prosthesis and fusion, and two others resolved in due course without additional surgery. The unacceptably high incidence of discitis may have been associated with technical aspects of preoperative discography, which our radiologists were newly initiating in our facility, or from intraoperative use of overhead-tracked radiography equipment. With modernization of our discographic techniques and removal of overhead radiography equipment from our operating theaters, postoperative discitis has been virtually eliminated.

There is always the possibility that if the patient population under consideration had been subjected to present-day stress and risk assessment, a predictability rating, and a physical predictability examination, some of the patients destined for fair and poor outcomes would have been excluded from surgery and results may have been better. In spite of that, more than 90% of the patients were disabled from work at the time of surgery and more than 90% became employed full time after surgery, with only 5% remaining unemployed. The number of patients who believed that the procedure had been worthwhile was essentially the same as the return to work percentage, ie, 95%.

CONCLUSIONS

In many ways, the Fernström procedure was probably ahead of its time, insofar as available diagnostic means often did not reveal pathology that could interfere with a successful surgical outcome. None of the complications that developed in this series seems peculiar to the procedure itself. The steel ball itself has been shown to be innocuous when properly sized and properly placed in a suitably prepared intervertebral disc space. The results in this series were somewhat better in patients who had disc protrusions in otherwise intact spines, but a high percentage of good and excellent results were seen in patients with moderate degenerative spinal changes and instability, for whom the alternative treatment probably would have been a spinal fusion. Fernström's procedure probably deserves future consideration as a means of augmenting discectomy where instability is likely, and in assisting management of the patient with disc-generated pain and instability with early or moderate facet arthritis.

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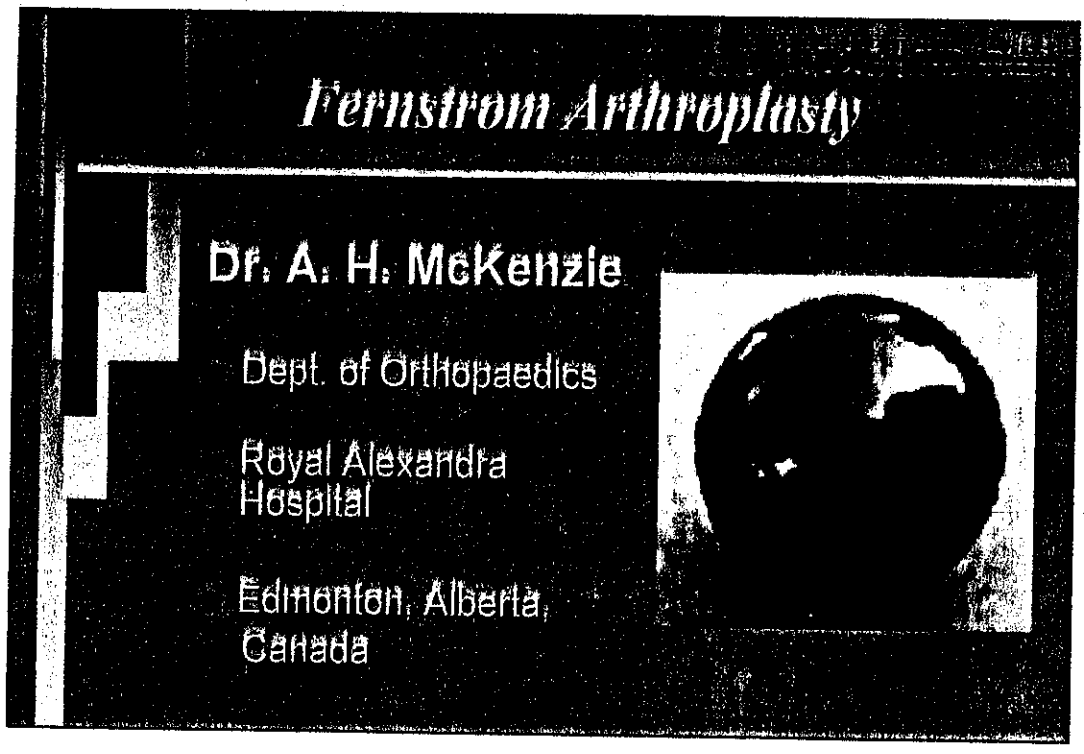

Gentlemen …

Thank you very much for inviting me to meet with you today and present what I hope will be an informative and exciting topic.

It is now 36 years since Ulf Fernstrom reported the use of his steel ball intervertebral disc prostheses in 105 patients with favourable early results.

This presentation touches on the evolution of intervertebral disc arthroplasty and the results of a long term follow-up study of my own series of 103 Fernstrom procedure patients.

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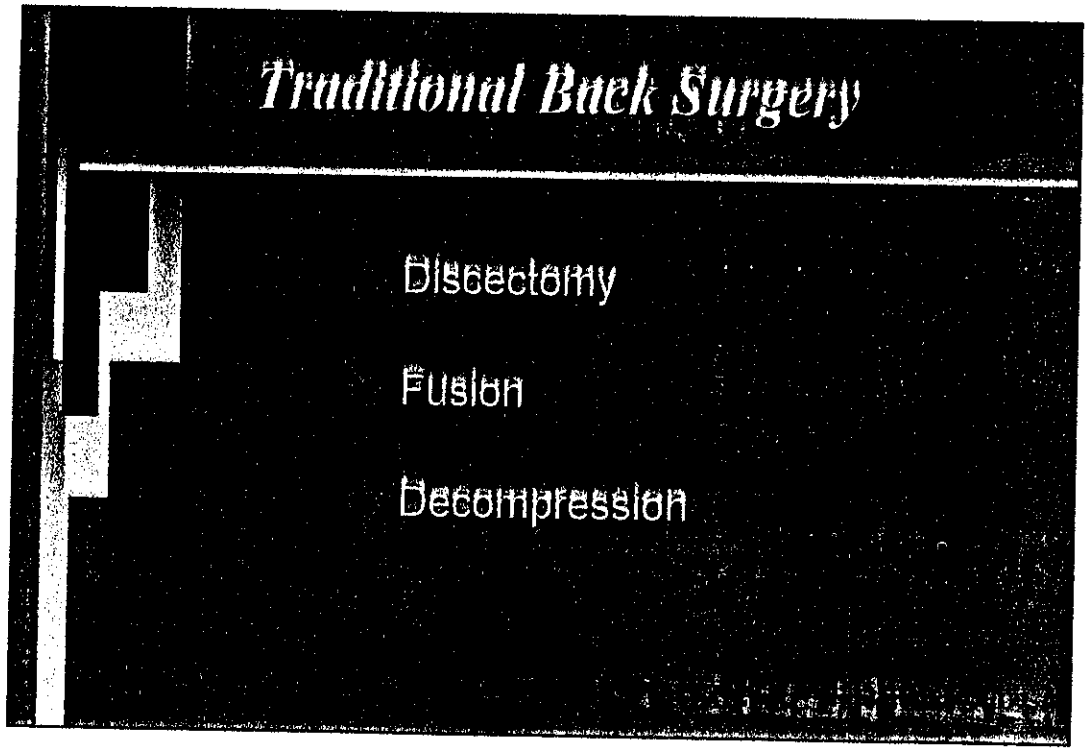
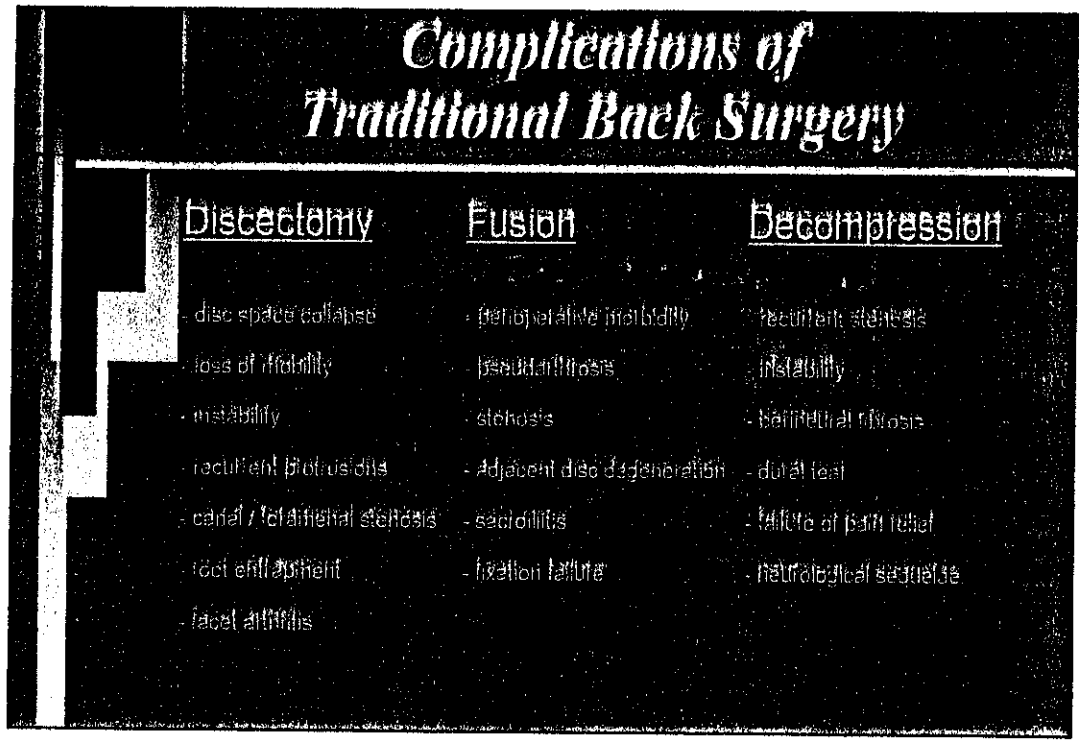


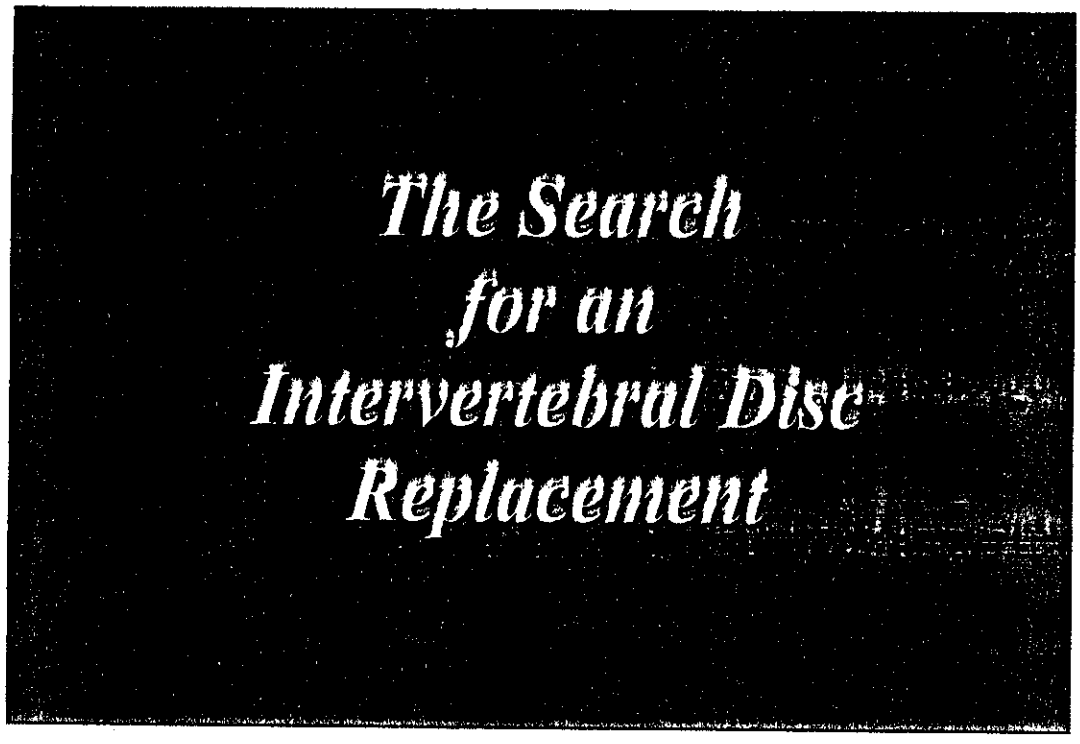
Where conservative treatment for the low back pain had failed, the traditional surgical alternatives were often a source of disappointment or disaster.

The ideal surgical alternative seemed to be one that would preserve or restore the normal healthy intervertebral disc.

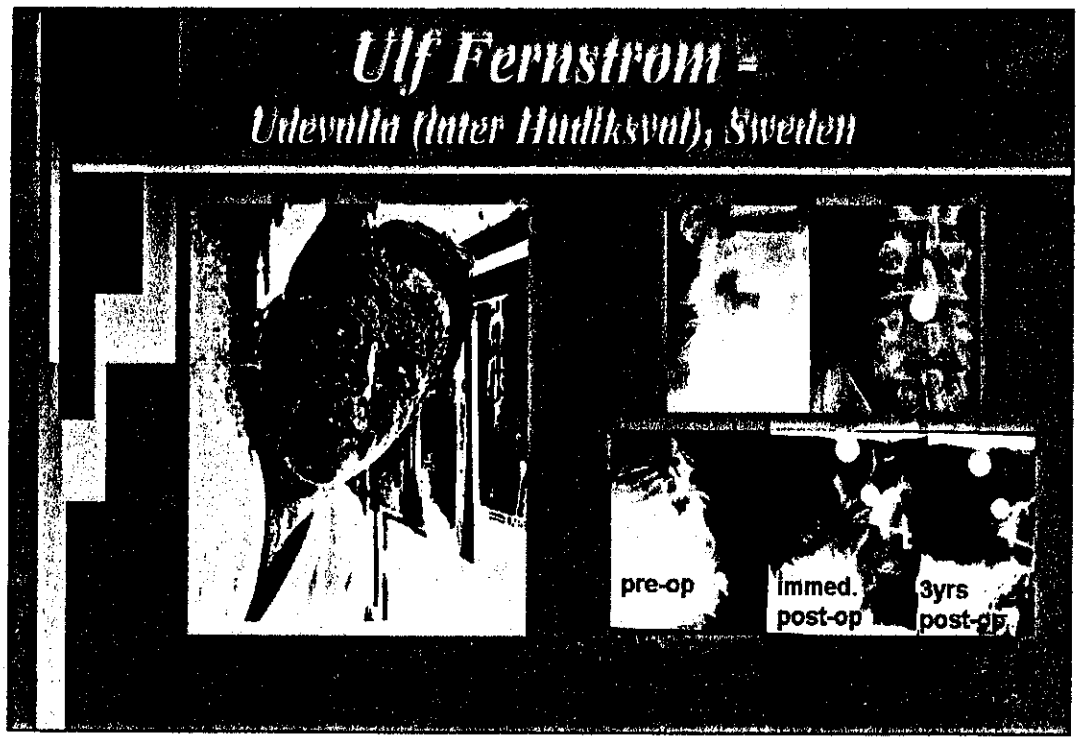
Discectomy, fusion, decompression, or some combination of these procedures did not regularly achieve normalcy of spinal function …



… but offered a host of complications.



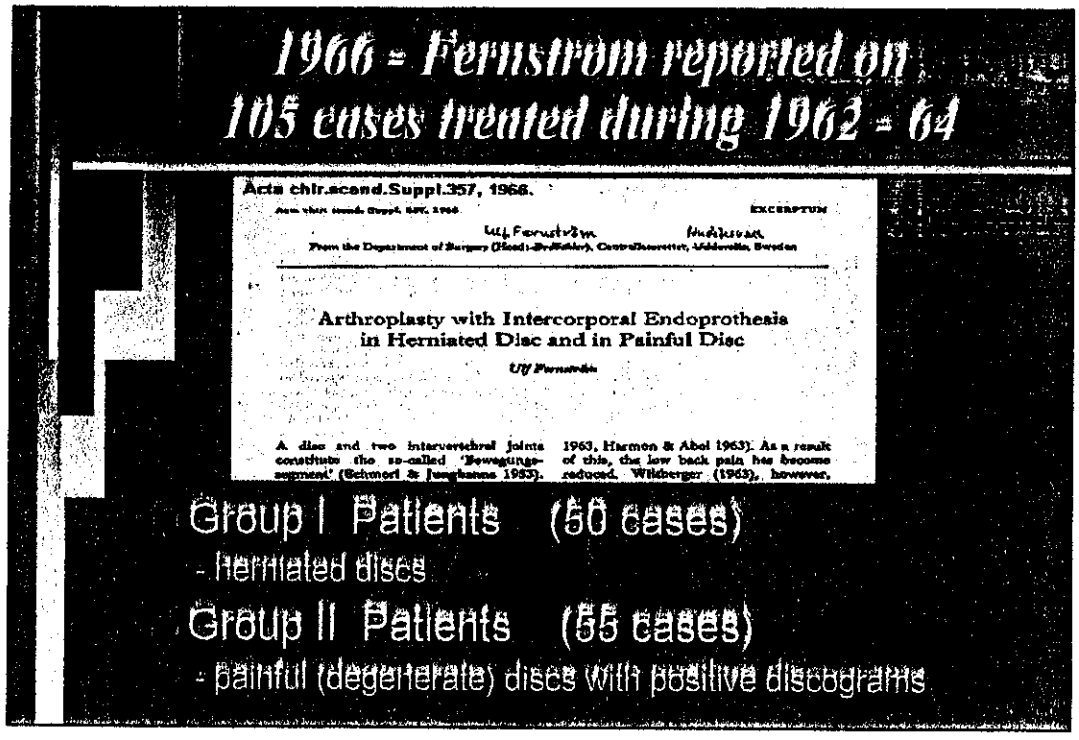
Ever since Mixter & Barr set surgeons upon discs, there has existed a need to not only deal with the effects of discs gone bad, but to find a way to restore their function.



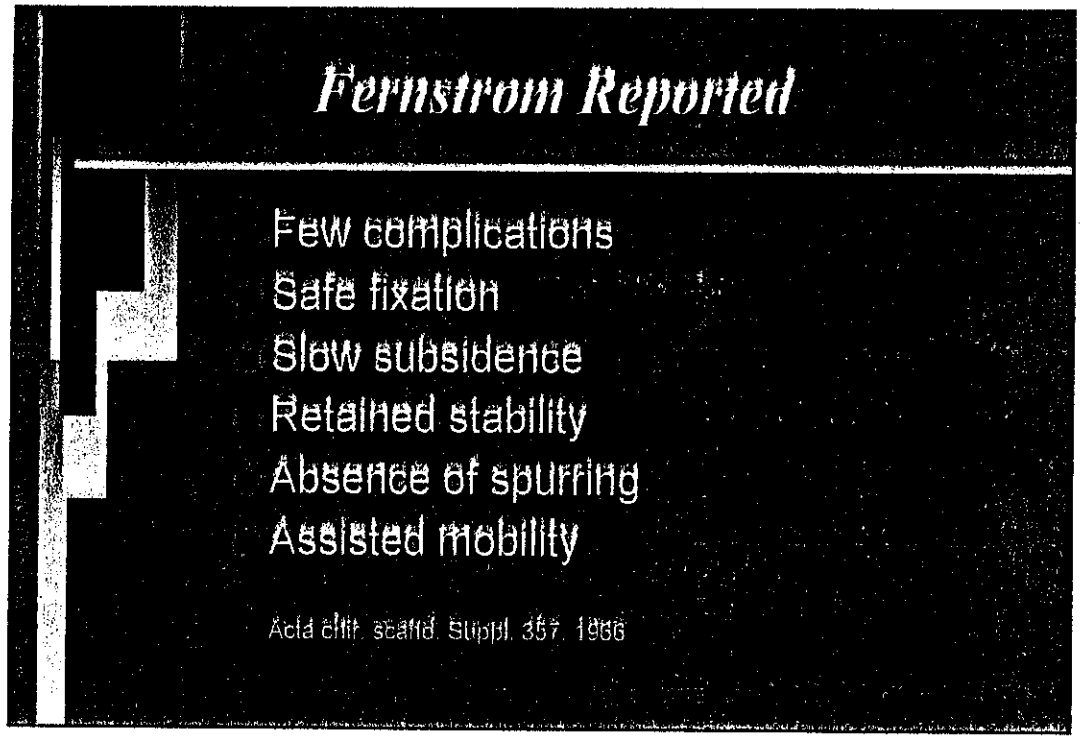
The most inventive of these pioneers of disc arthroplasty was a Swedish general surgeon from Udevalla University in Sweden, Ulf Fernstrom.

With his steel balls, he successfully used a standard posterior approach and treated a patient group, 85% of whom were on full disability pensions for back problems from disc protrusions and degenerative painful disc rupture, usually with instability and always with positive discograms.

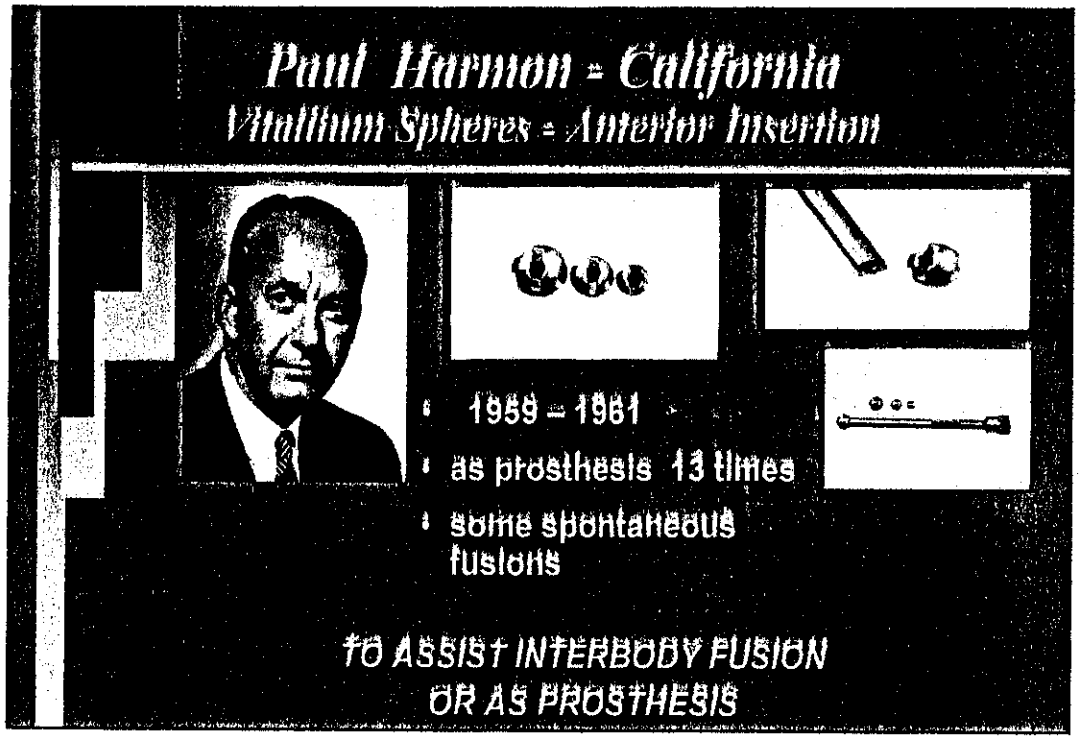
He restored 85% of these patients to gainful employment.



His first 105 patients were comprised of 50 with herniated discs and 55 with painful discs proved by discography.



His report immediately drew admiration from California, South Africa and Canada, but aroused a severe backlash from the Swedish spinal community.



Paul Harmon had preceded Fernstrom in recognizing the value of the nuclear recess for the use of uncompressible spheres in the spine.

Initially he used them as a substitute for his fibular grafts to prevent collapse of the cancellous bone he used to encourage anterior spinal fusion. In some cases he left it as a prosthesis.

He told me that he had discontinued the procedure only because his hospital and insurance company had been worried about potential litigation.

In South Africa, Reitz & Joubert used a few steel balls that were small and allowed disc collapse.

They later tried hemispheres and silastic "UFO's" to retain disc height. Their hemispheres and "UFO's" were unstable and failed.

Other designs are on trial but long term results are not in.

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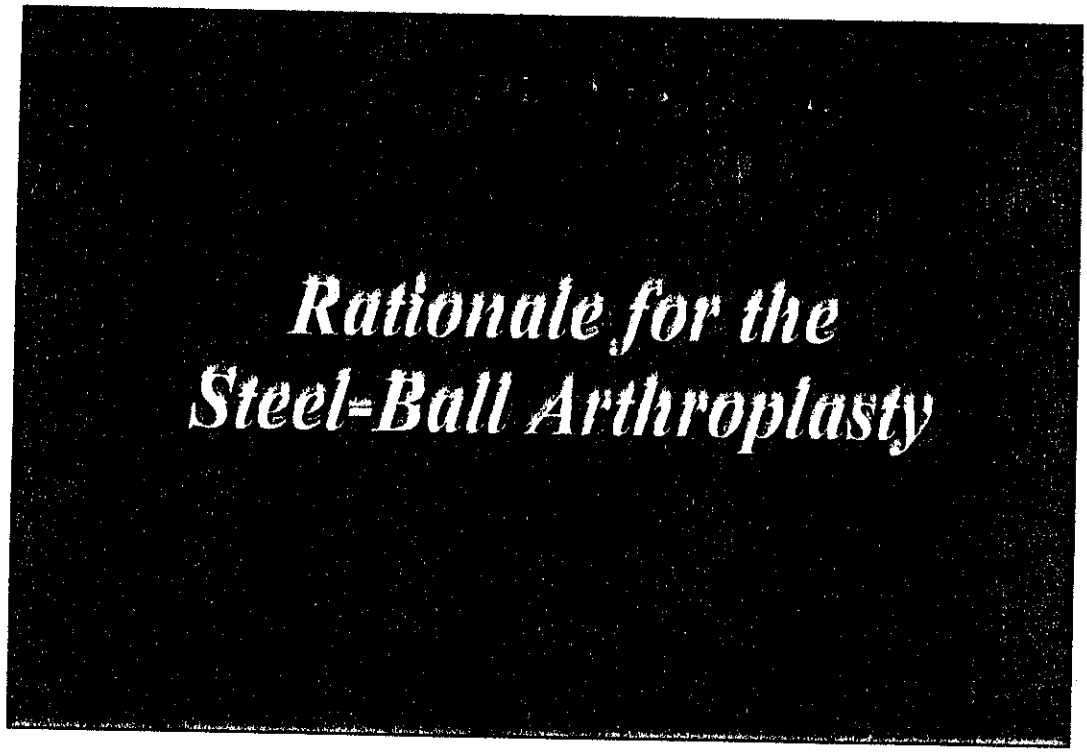
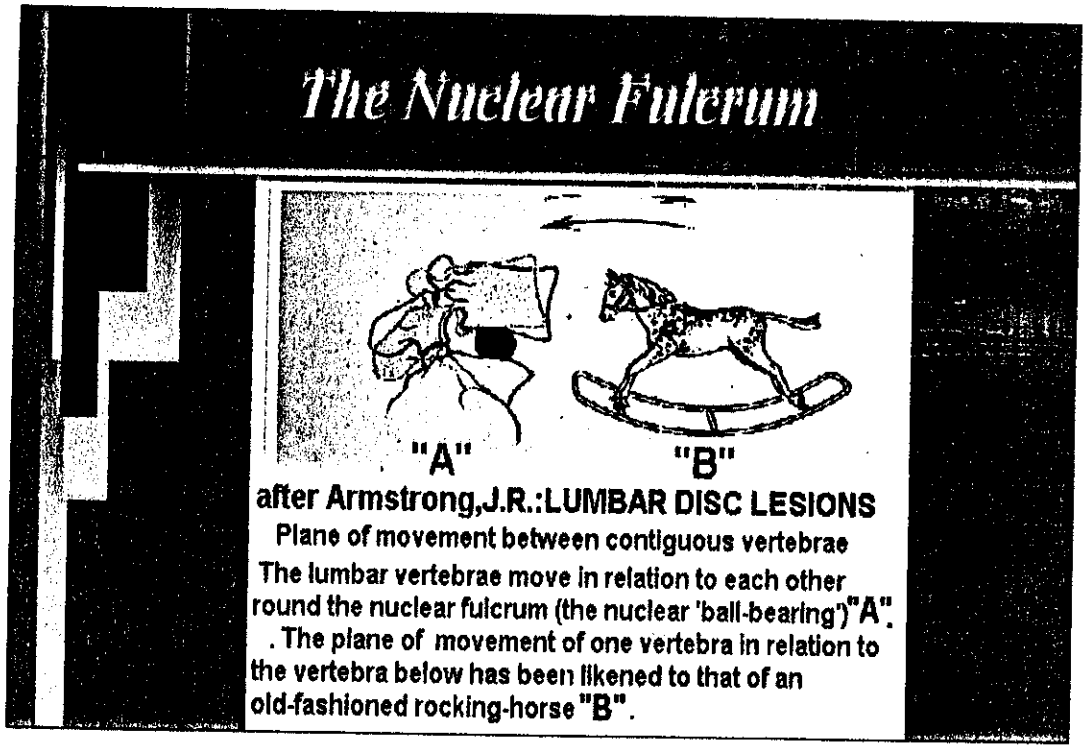


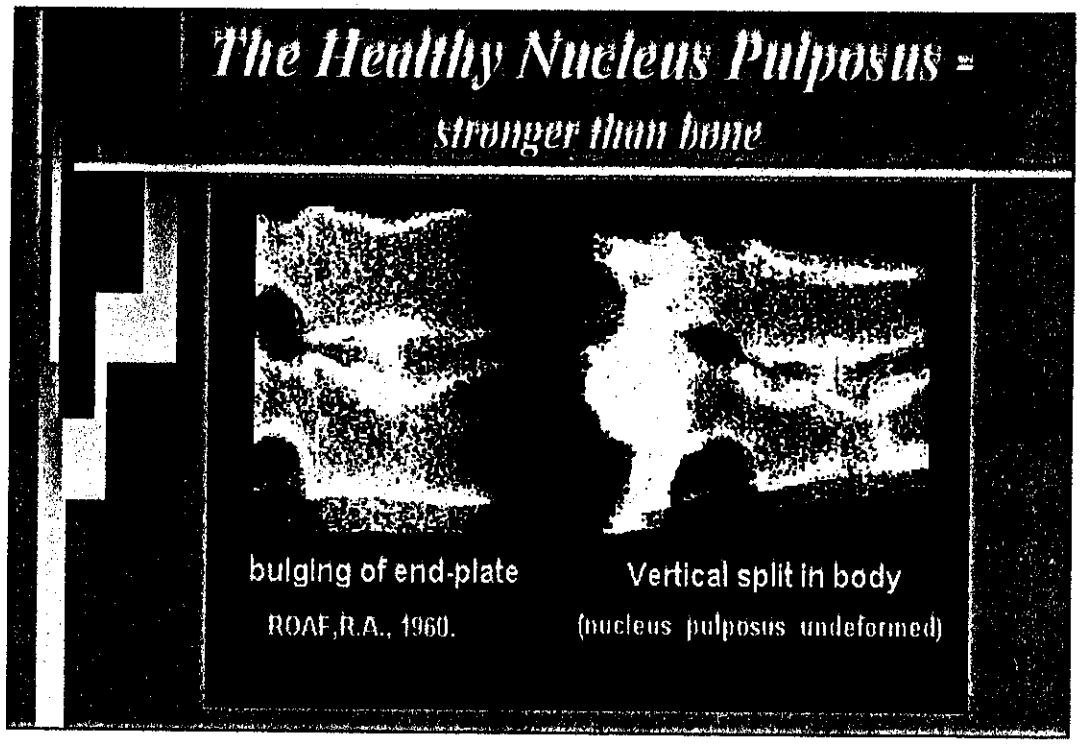
Fernstrom stayed with the steel ball for a number of reasons …



Fernstrom's reasons for selecting the steel ball included Harmon's observation of gaining stability by restoring tension on the annulus.

He was also convinced that Armstrong's observations that the nuclear fulcrum could be simulated by a steel ball in the nuclear recess had been correct for a young healthy disc.

He knew that in aged discs the centre of motion was not constant, but he felt that the steel ball could adapt to minor variations in the centre of motion.



Fernstrom felt that restoration of the nucleus required an incompressible device. Harmon agreed with this concept.

They anticipated that the vertebrae could withstand a steel ball because Roaf had already shown that a healthy nuclear pulposus was harder than bone.

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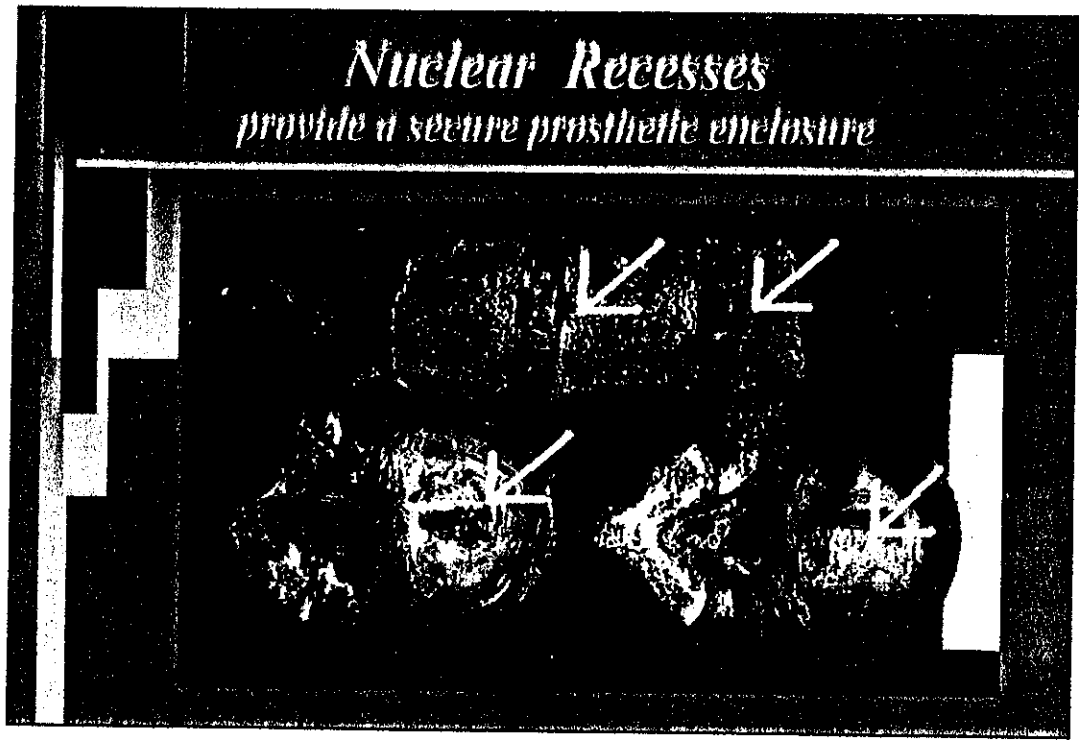

Both Fernstrom and Harmon had observed that the nuclear recess provided a convenient secure seating for the steel balls …

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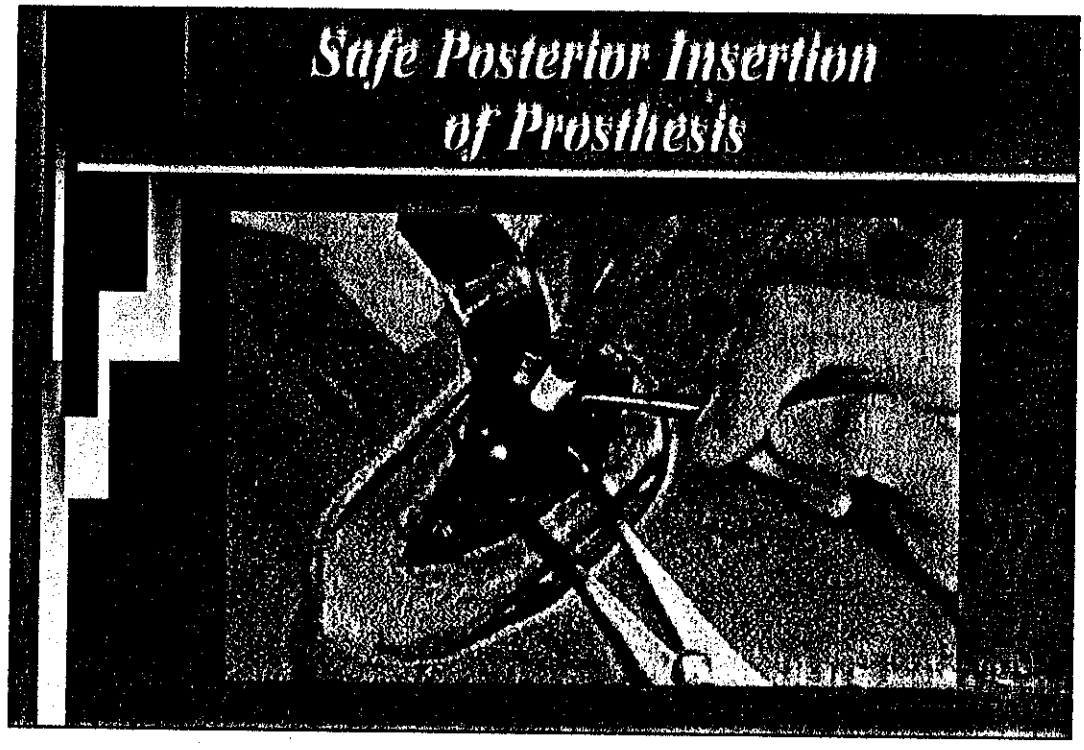

… and as Fernstrom had demonstrated, they could be safely inserted through a limited posterior discectomy approach. .

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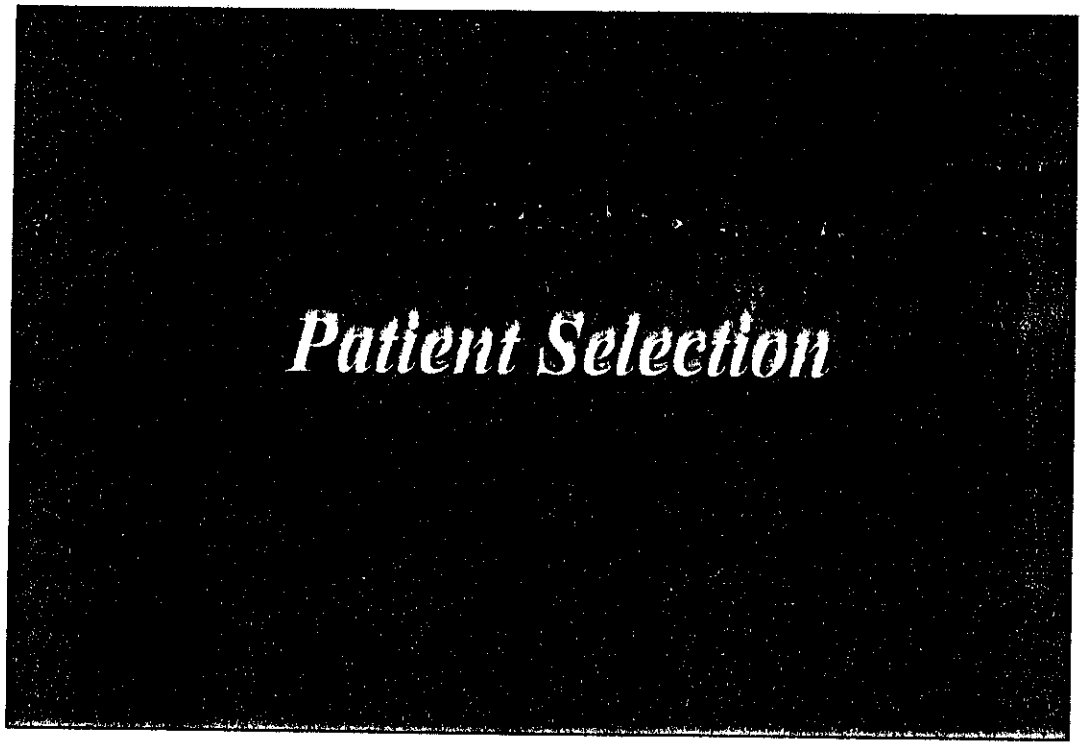

Patient selection followed by Fernstrom, and later by myself …

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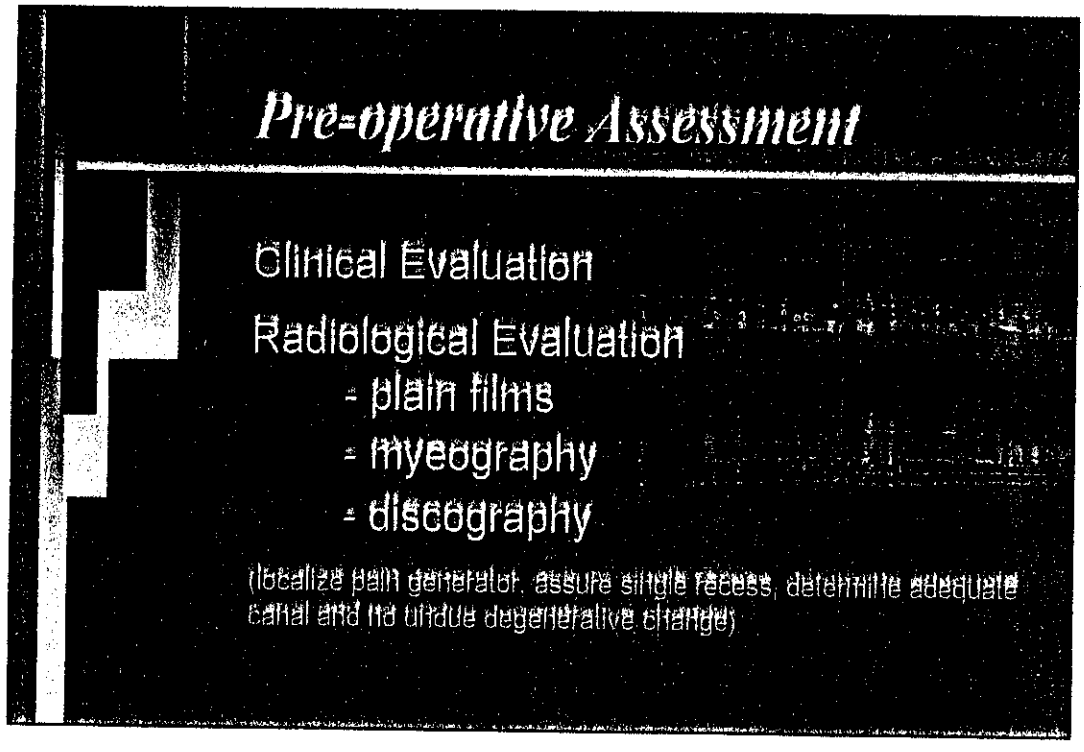

… depended upon accepted clinical and radiological criteria of the day for surgical treatment of disc protrusions (Group I patients), or for treatment by spinal fusion (Group II patients).

Group II patients also demonstrated a positive result on discography.

We tried to avoid gross vertebral body and facet osteophytes.

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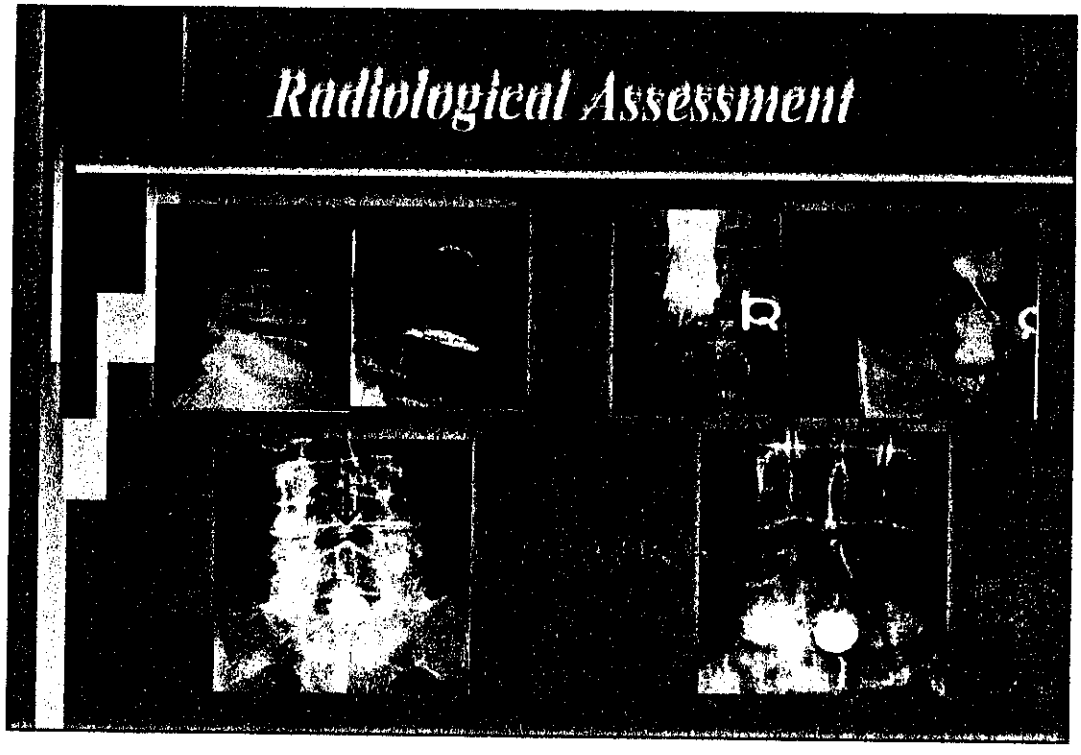

We required radiological evidence of adequate width of the spinal canal and the presence of one central nuclear recess.

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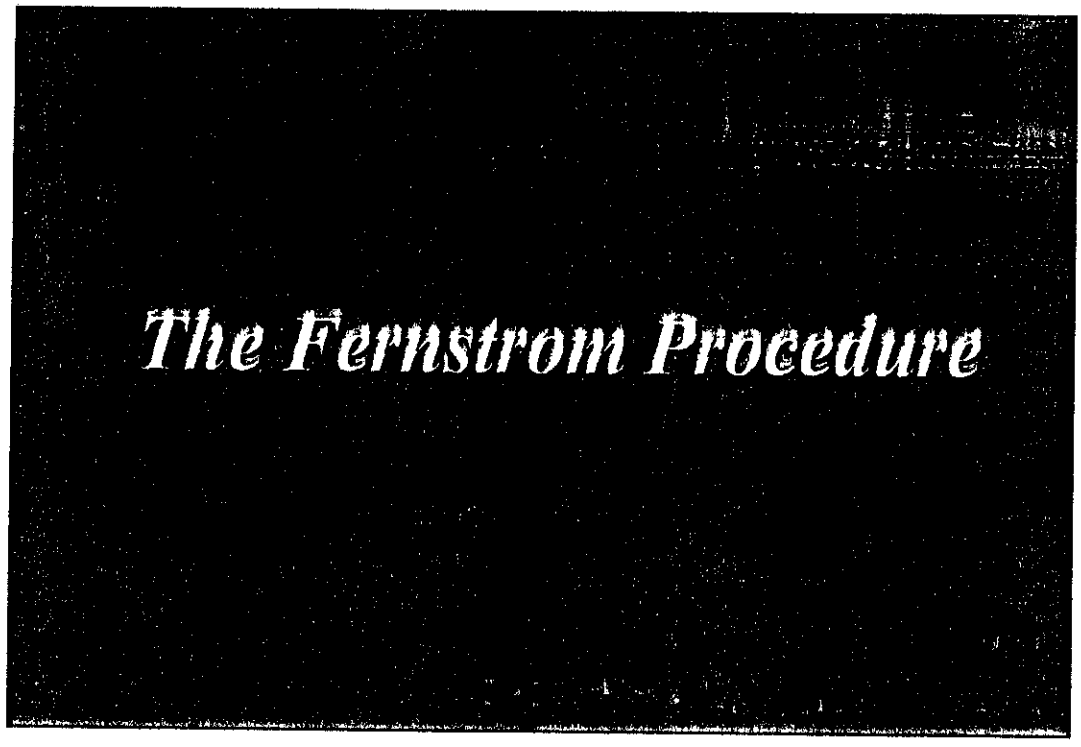
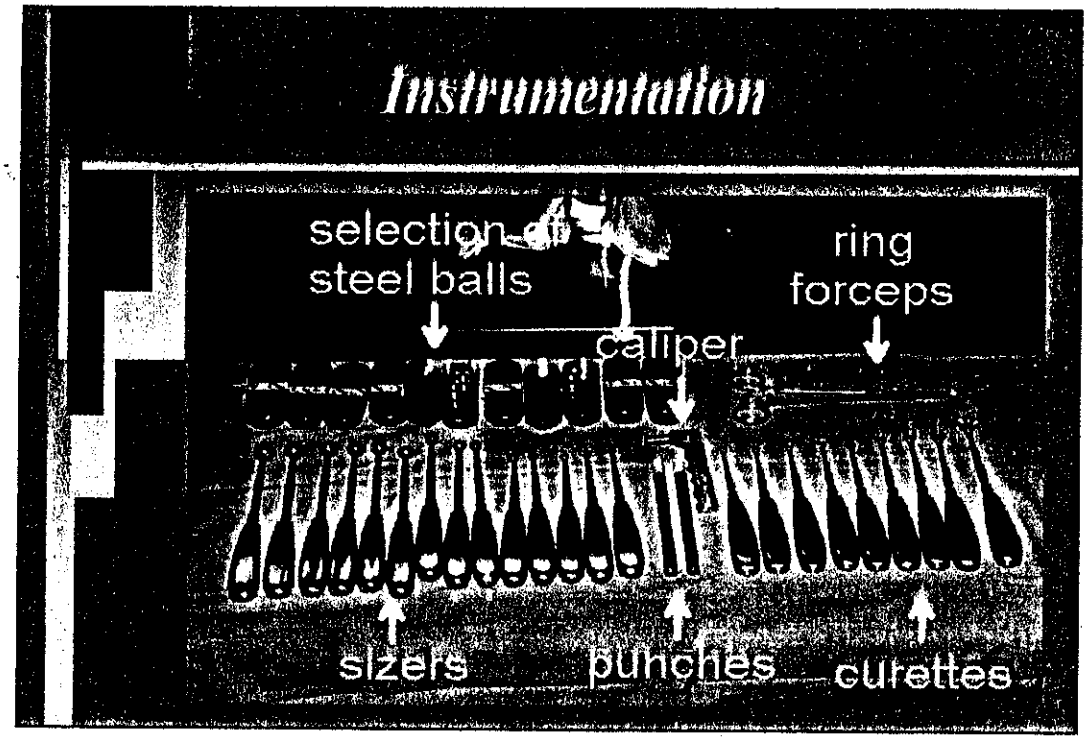


As for the Fernstrom procedure itself, the patient was positioned in the prone attitude with lumbar flexion to neutral and the abdomen free of pressure.



Instrumentation consisted of standard laminectomy/discectomy instruments and retractors, a large Cloward spreader, Fernstrom's curettes, sizers, punches and steel balls, usually 10 to 15 millimeters in size.

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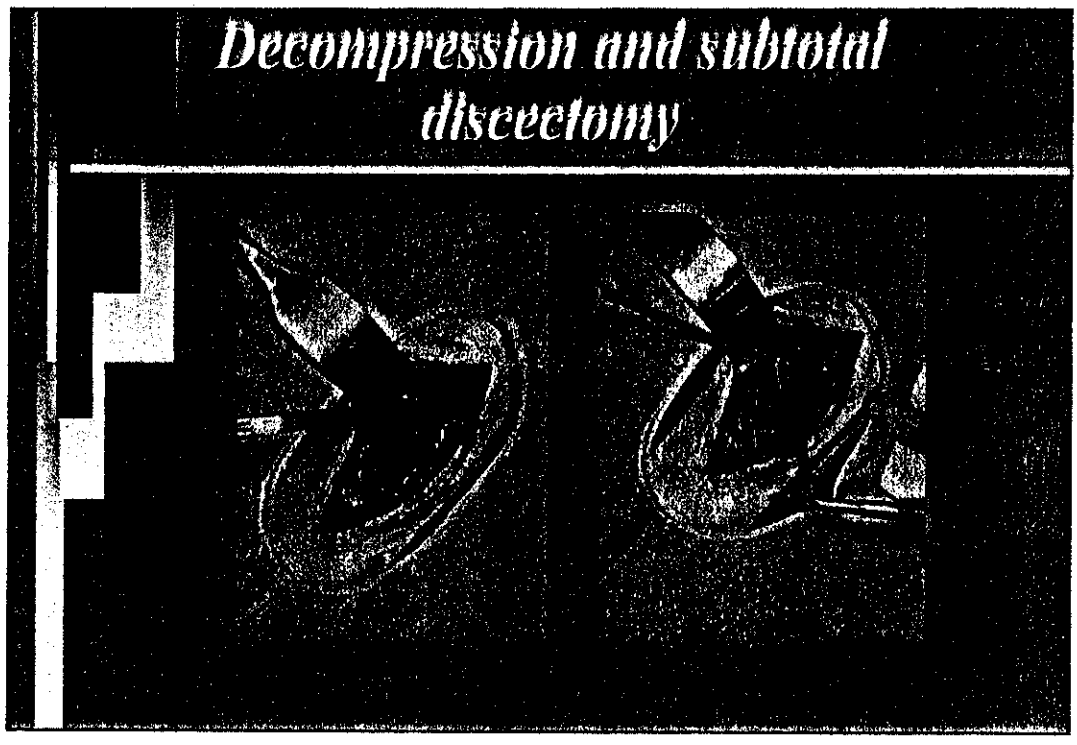

Following laminotomy and discectomy …

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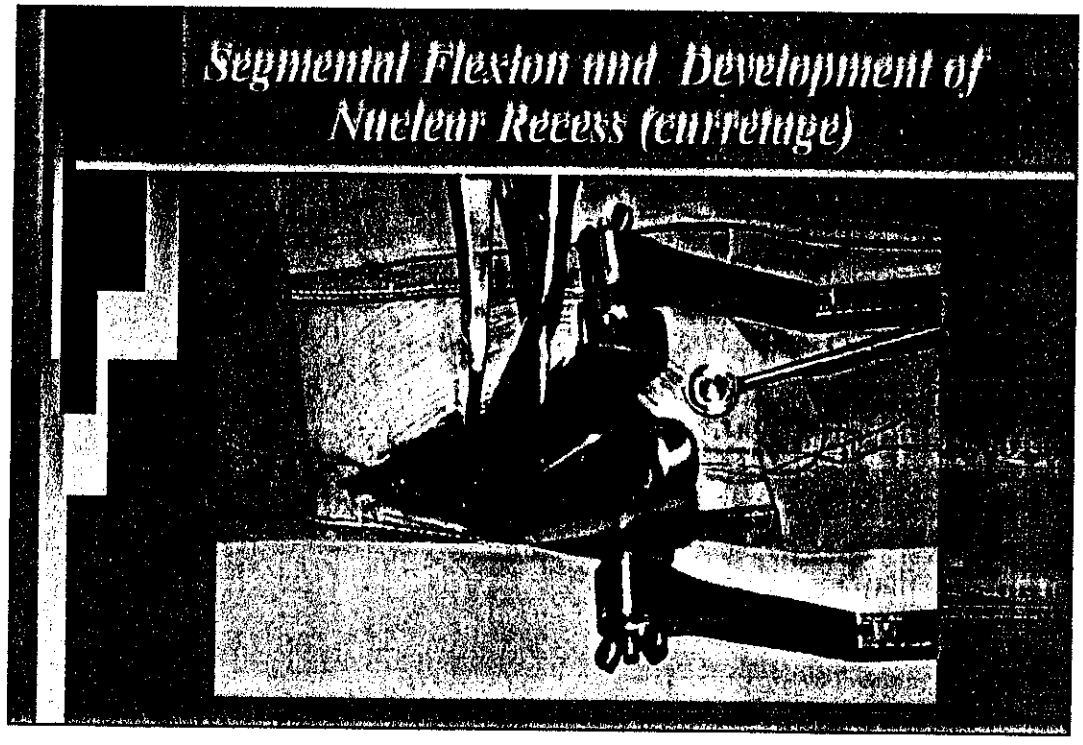

Cloward's interspinous spreader was used for segmental flexion and to aid completion of discectomy, including meticulous curettage of the nuclear recess with sized hemispherical curettes, preserving all possible articular cartilage.

The disc space was often gradually expanded with sizers.

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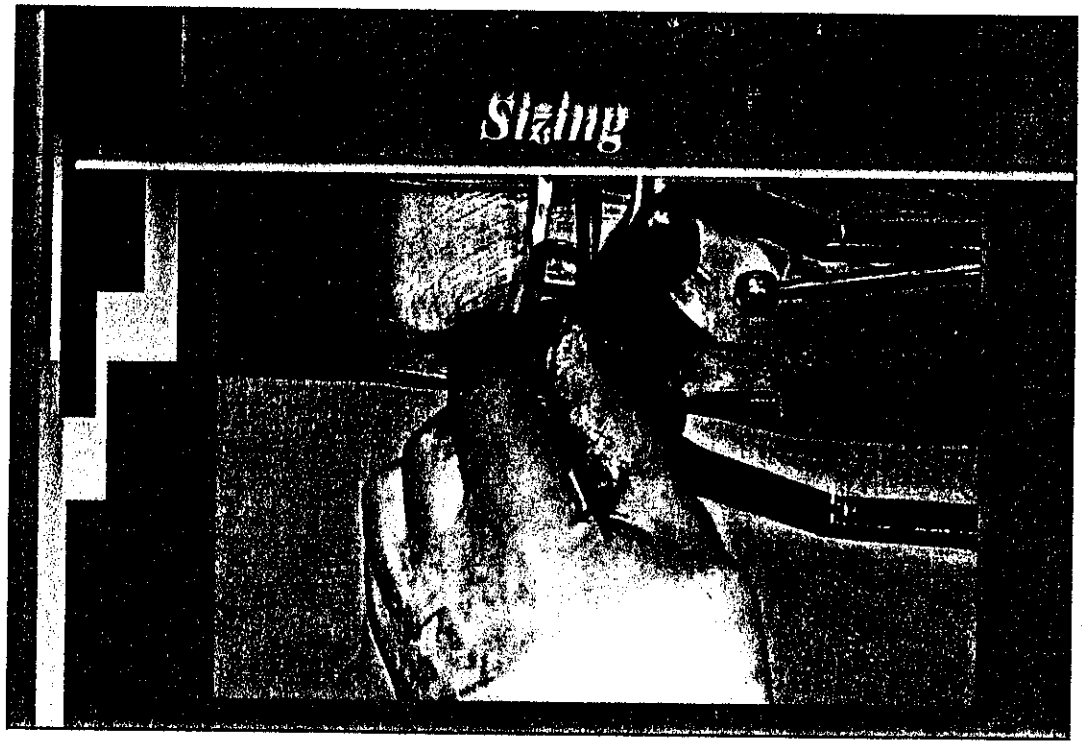

The elliptical sizers were then used to determine the appropriate size of steel ball.

A snug, stable fit was required.

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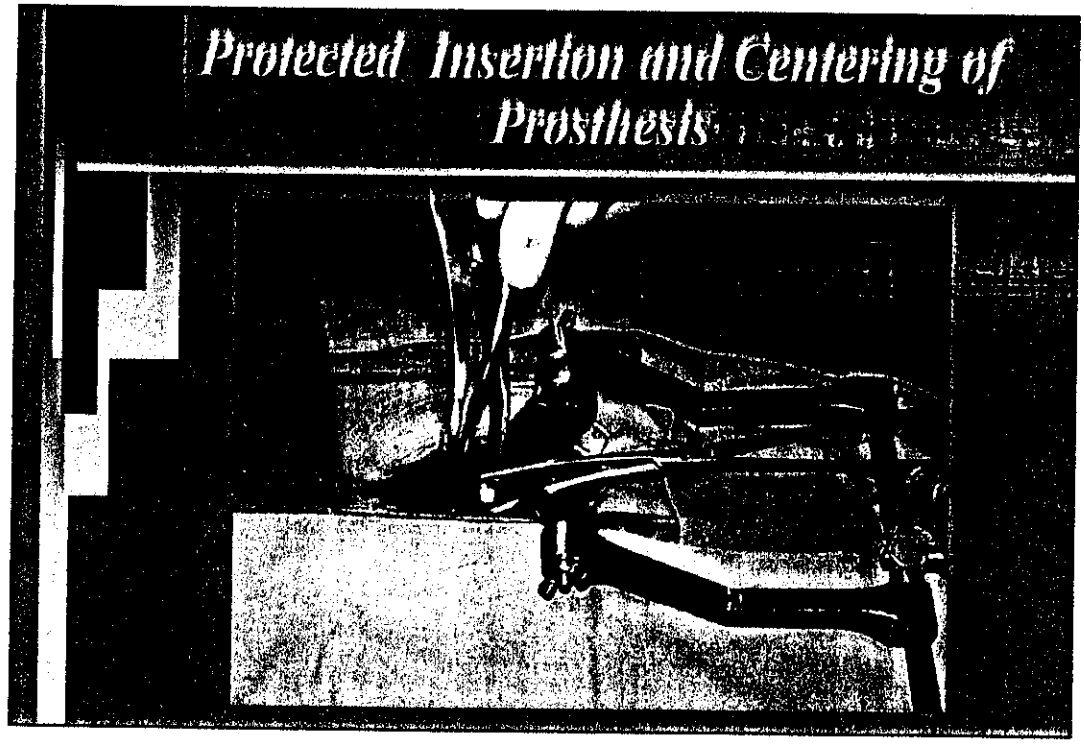

The appropriate steel ball could then be inserted past the nerve root and dura, protected by the nerve root retractor in the annulus opening.

The ball might locate itself directly in the prepared nuclear recess or could require re-direction.

In any case, it would ultimately "snap" or "lock" in place.

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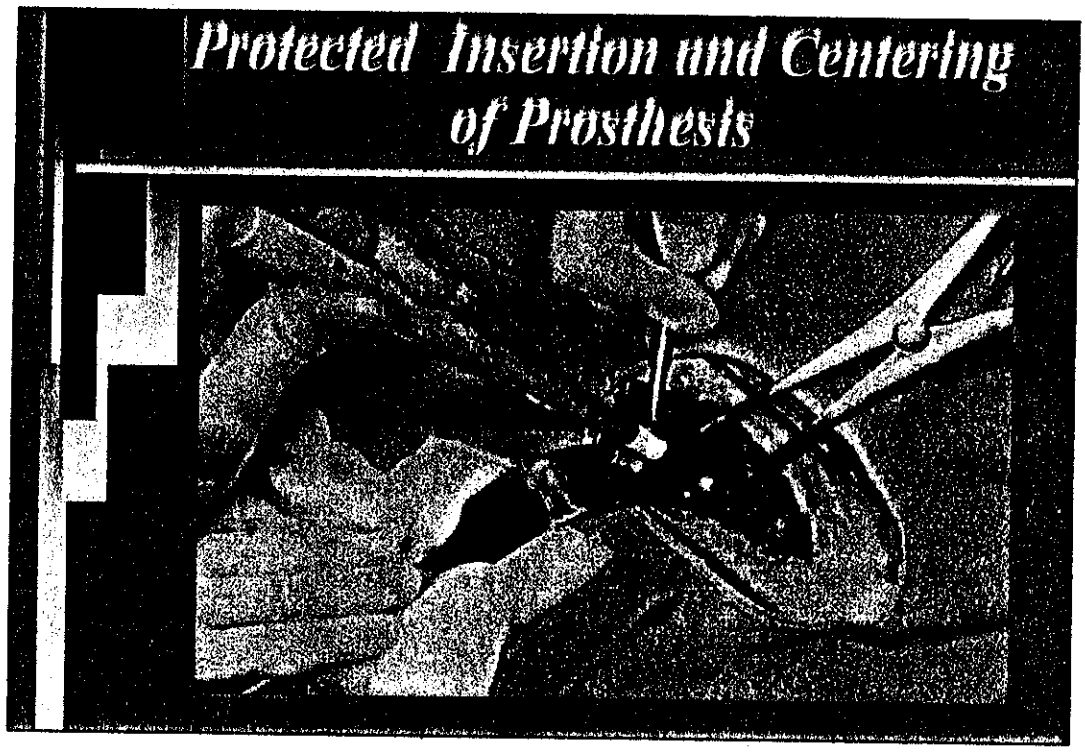
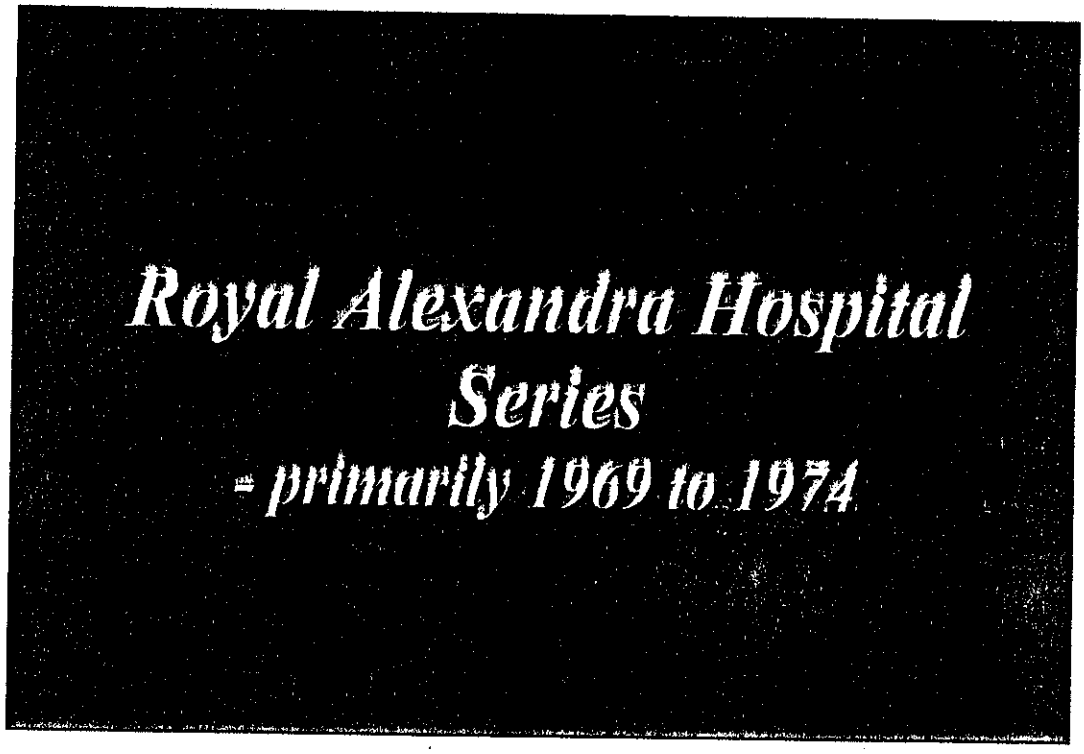
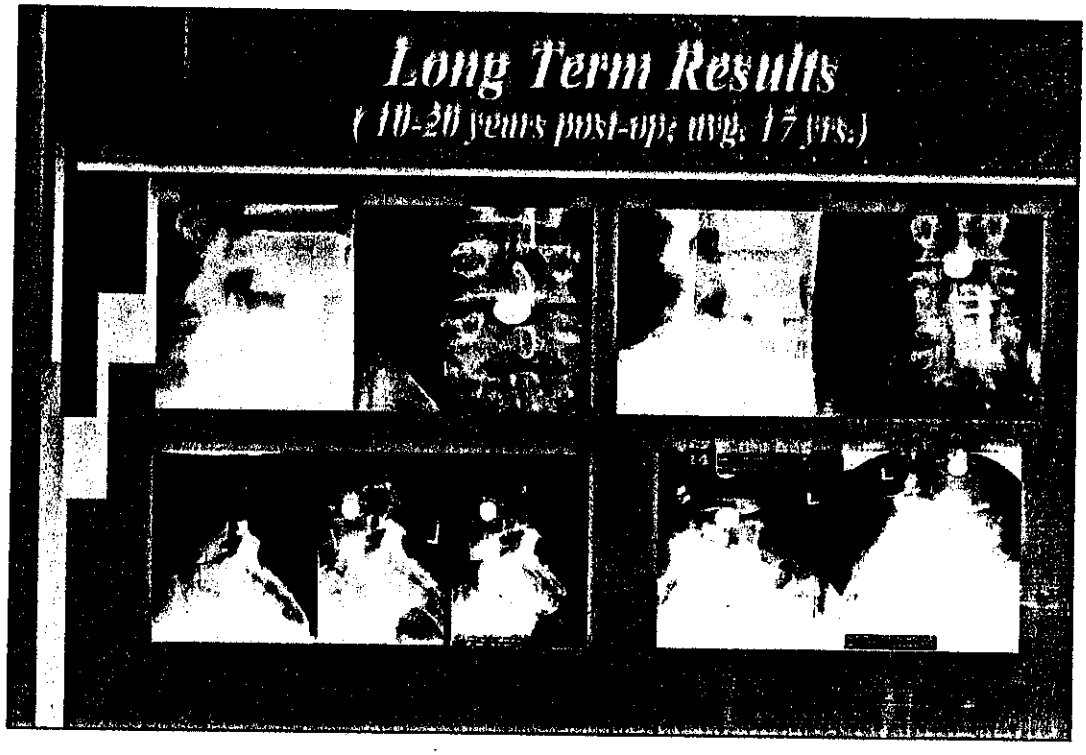


Here's another view, as a punch is about to be applied to seat the steel ball in position.



This next section profiles my own series of Fernstrom procedures performed at the Royal Alex Hospital in Edmonton, Canada.



This is the first long term assessment of Fernstrom's steel ball arthroplasty.

At the time of the study, my patients were 10 to 20 years post-op, with an average of about 17 years.

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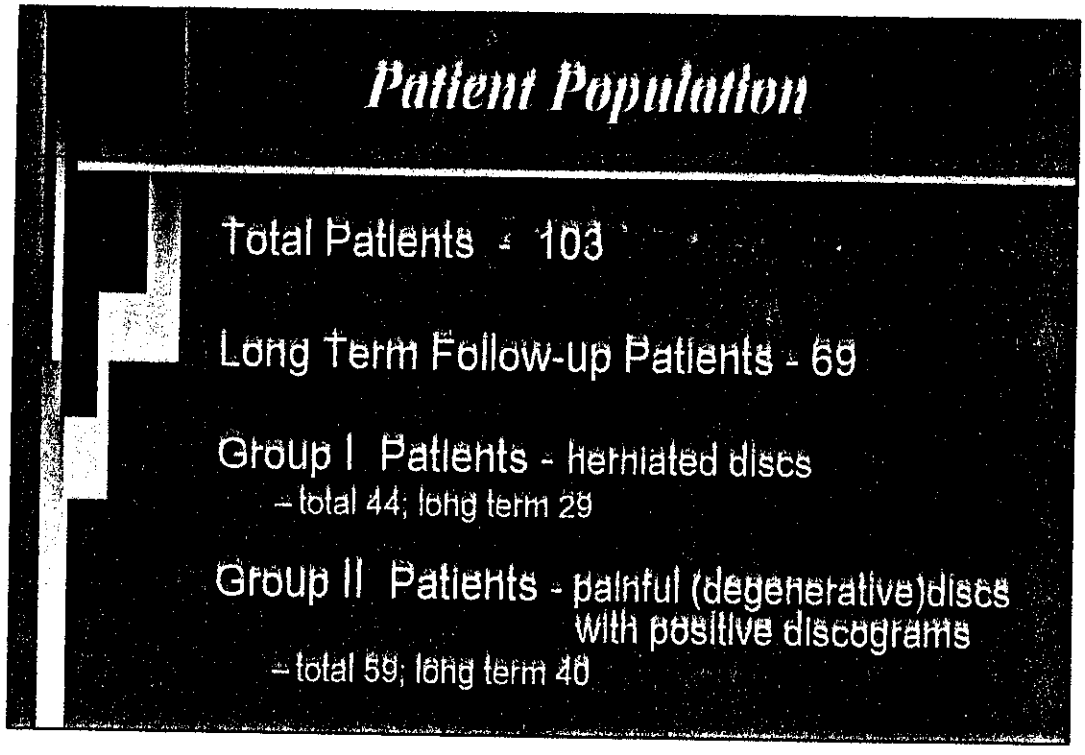
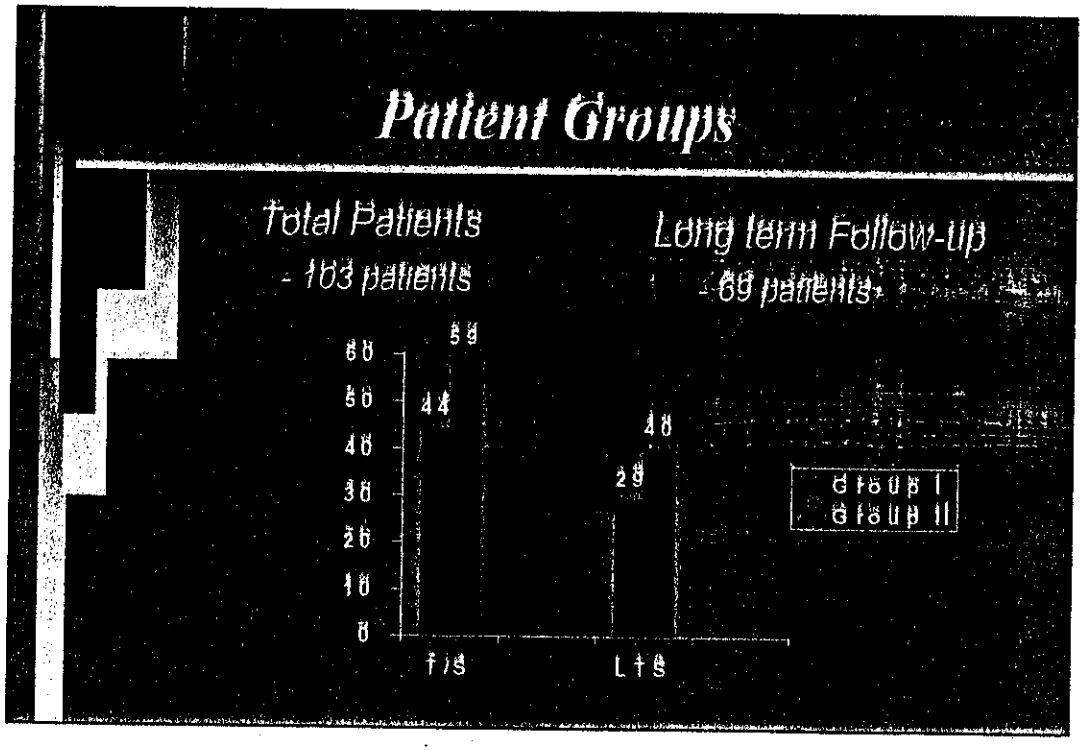


As you can imagine, follow-up of all patients on a long term basis was not possible. Considering the time interval from surgery to review, the overall patient response to the study seemed commendable. Many patients traveled long distances at personal expense in order to participate.

Of my total of 103 Fernstrom procedure patients, 69 were available for long term assessment.

Using Fernstrom's pre-op categorization, patients were considered Class I or Class II depending on their pre-operative condition. Group I were those with disc protrusions, while Group II were those with degenerative disc disease who would otherwise have qualified for spinal fusion.



Here are the same numbers presented graphically. You can see that the relative proportion of Group I vs. Group II patients in the total series and long term follow-up series are very similar.

Also, the large sample size of long term follow-up patients relative to the total probably adds to the reliability of the results.

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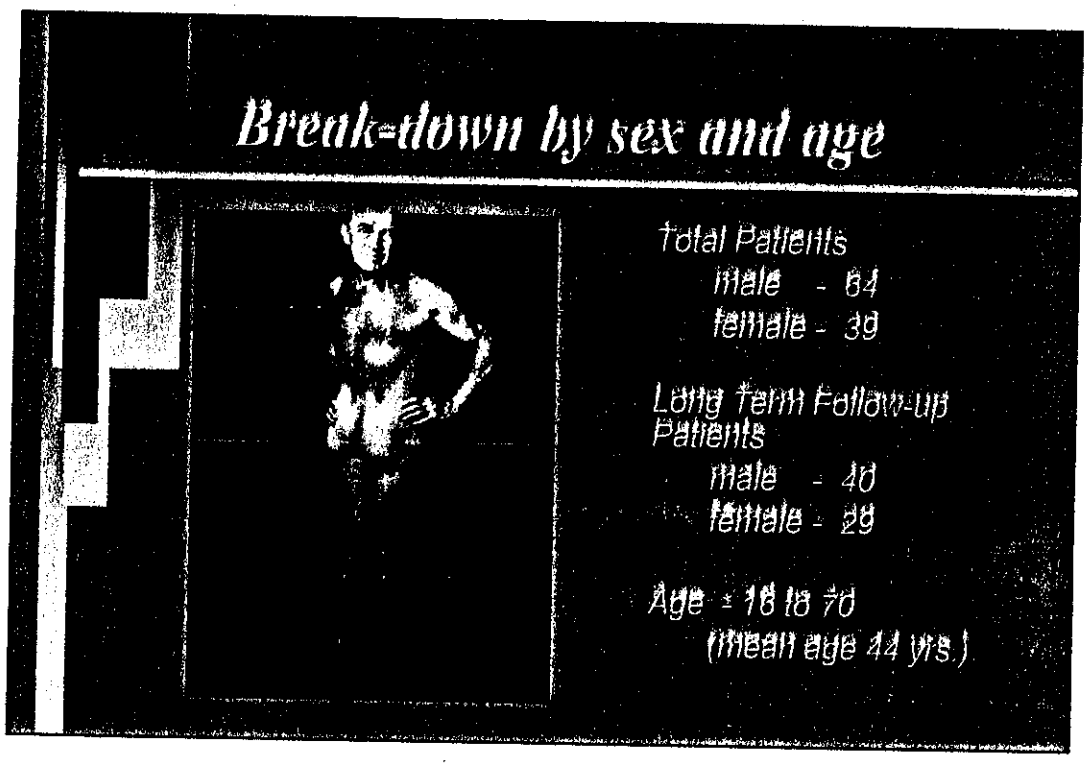
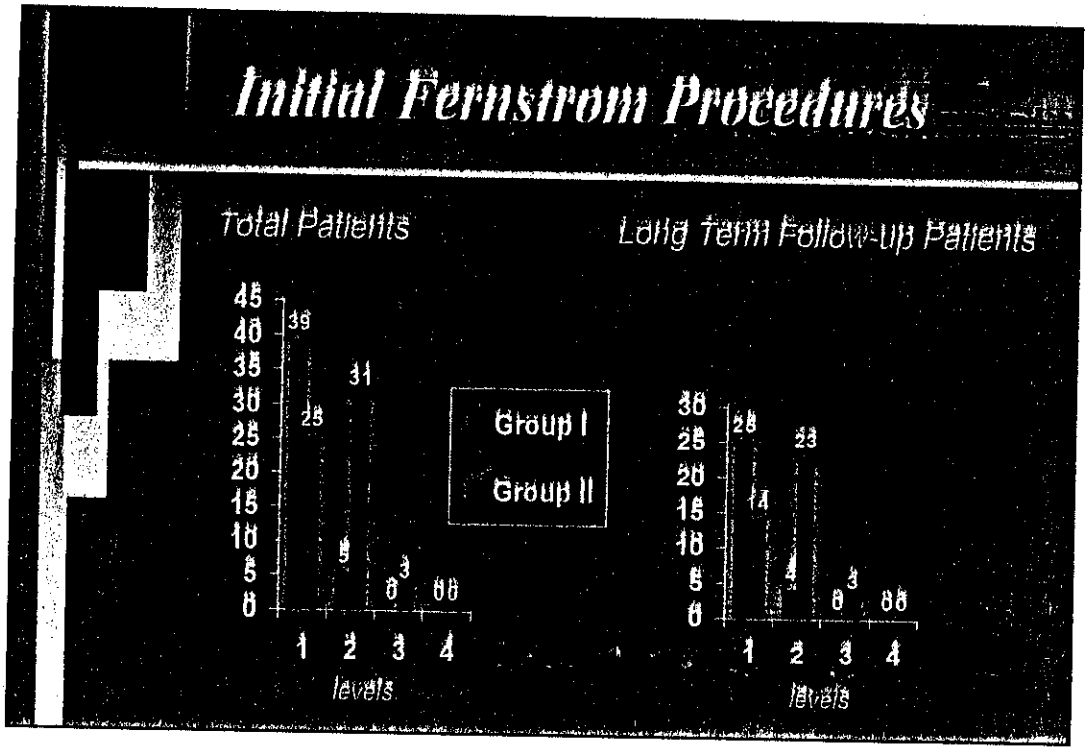


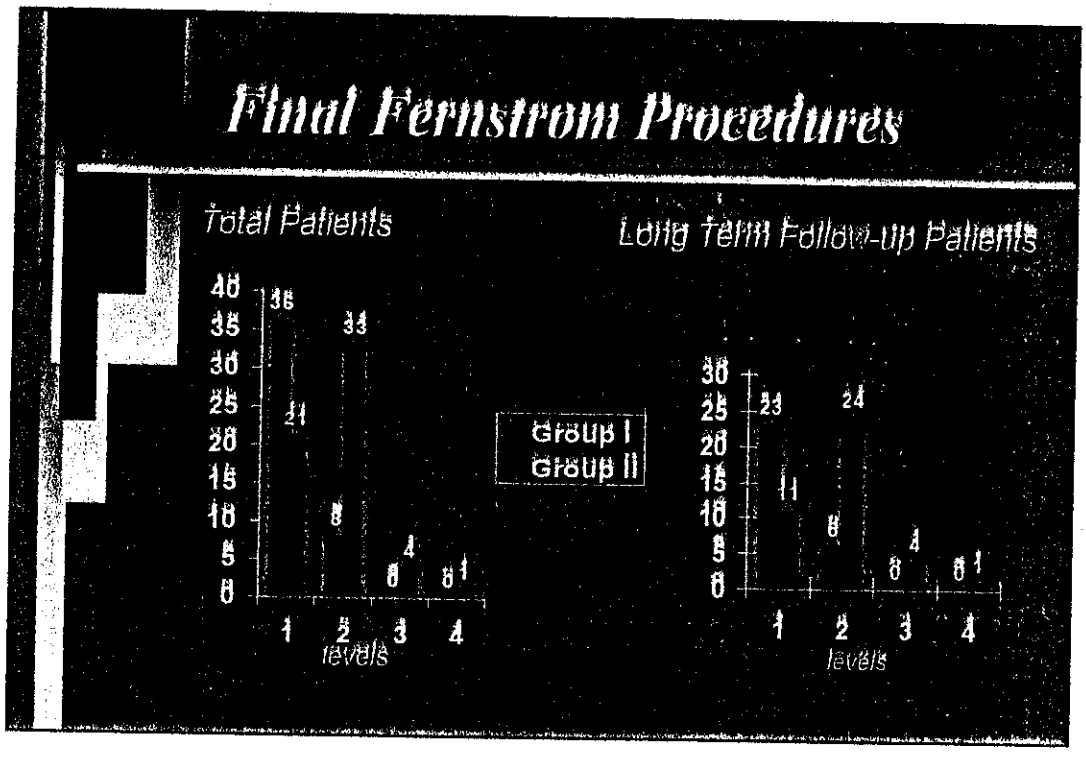
In determining the break-down by sex and age, it was observed that most patients had some break-down due to both of these factors.

About 60% of patients were male, and the average age was about 44 years.



Initially this was the distribution of patients in Group I and Group II indicating those with procedures at one, two or three spinal levels. The proportions of Fernstrom procedures at one or more levels were comparable for both the total series of patients and the long term follow-up series.

As you would expect, patients in Group II were more likely than those in Group I to have an initial Fernstrom procedure at more than one level.



This is the eventual status of the patients in Group I and Group II showing the numbers in the total series and in the follow-up series that had one, two, three or four level prosthetic inserts.

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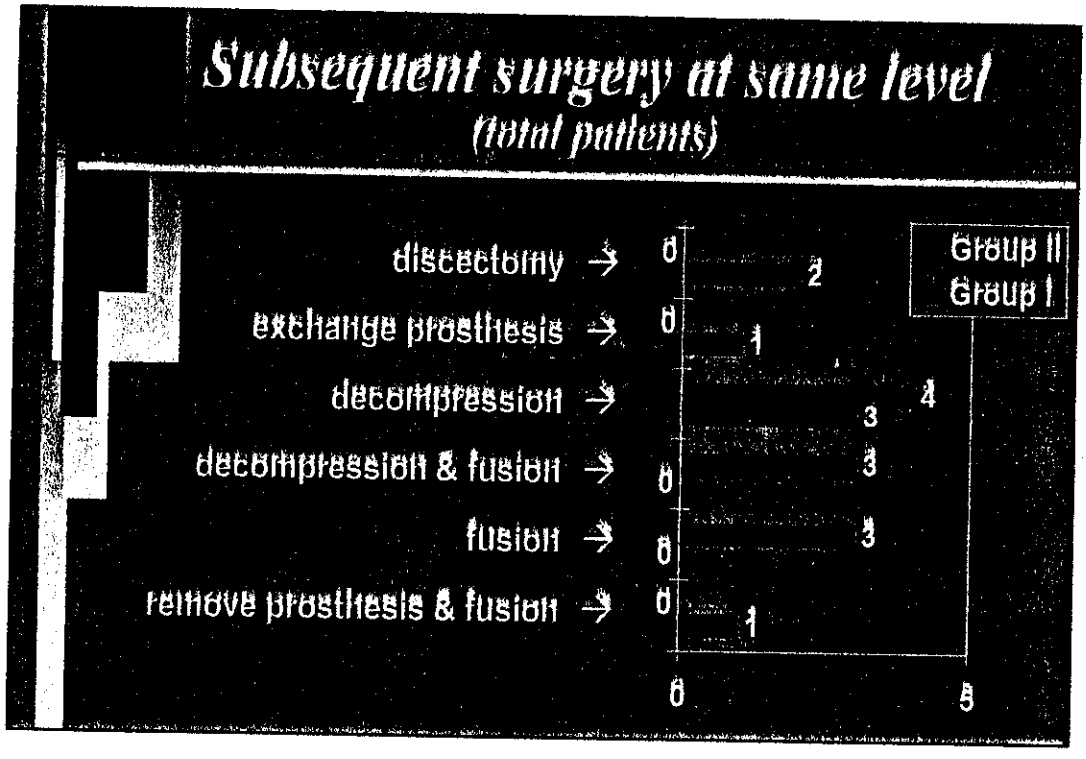
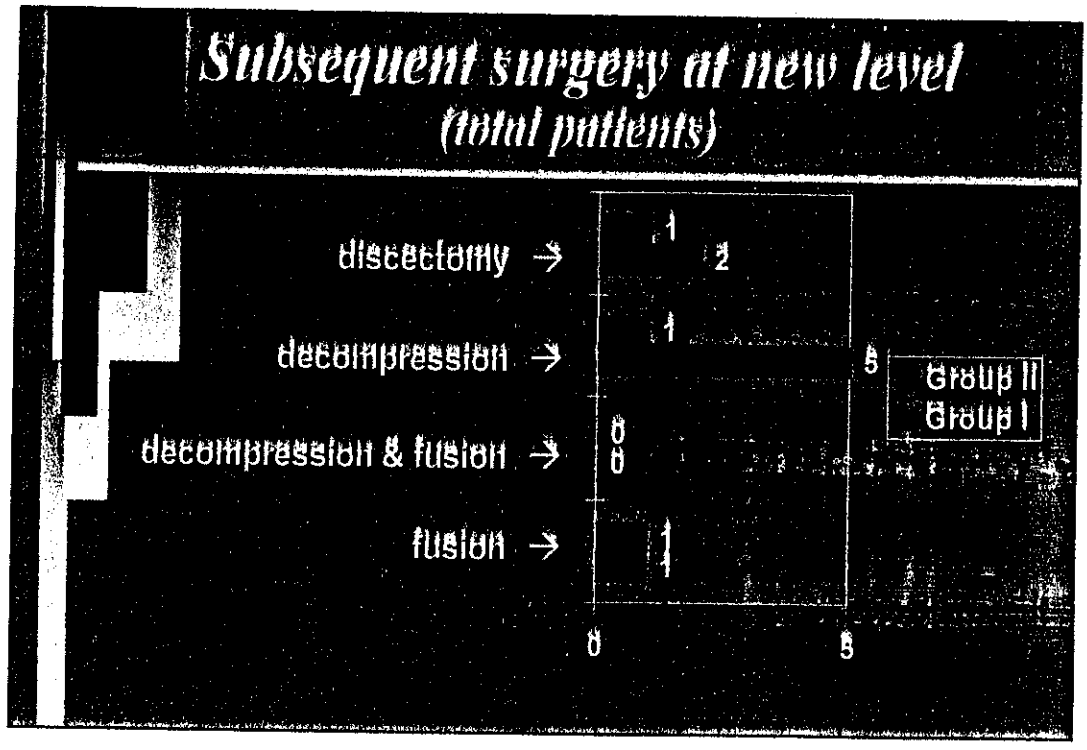


For those requiring subsequent surgery at the same level as the initial Fernstrom arthroplasty, decompression with or without fusion was the most commonly performed additional procedure.

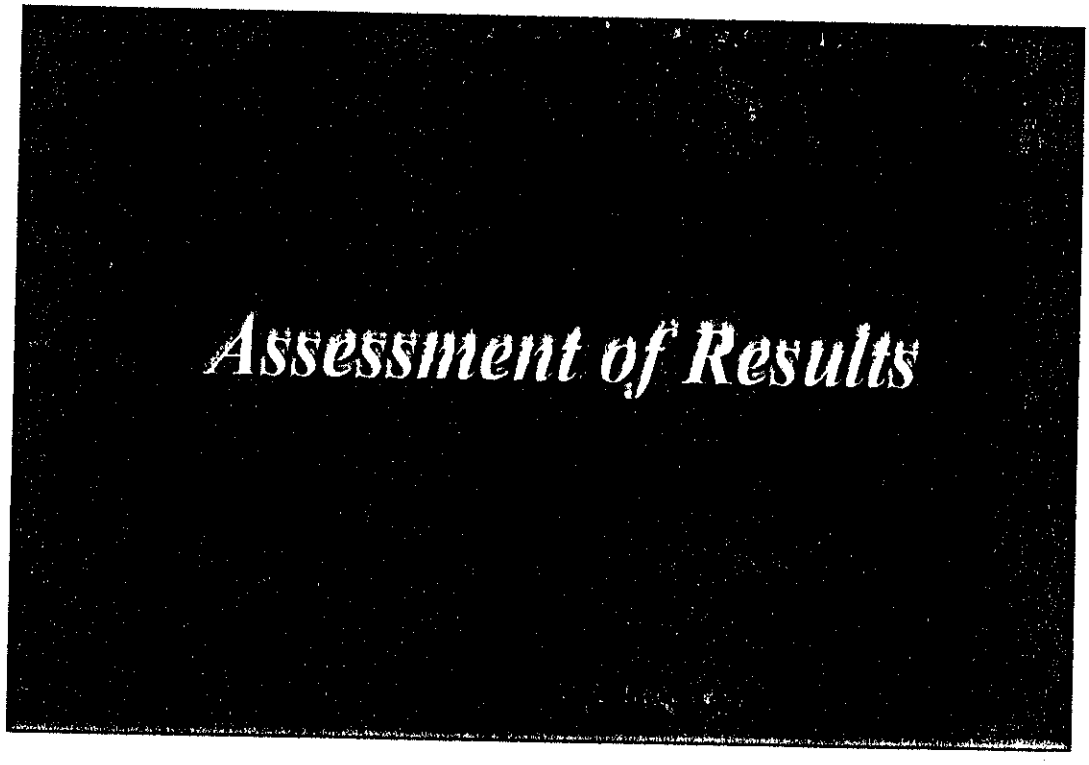
This reflects the changing awareness of spinal stenosis during the decade or so after most of the initial procedures had been completed.

Two surgeries were for recurrent disc protrusion and one for a subluxated prosthesis. All occurred early in series

Less than 10% of all patients ultimately required fusion.

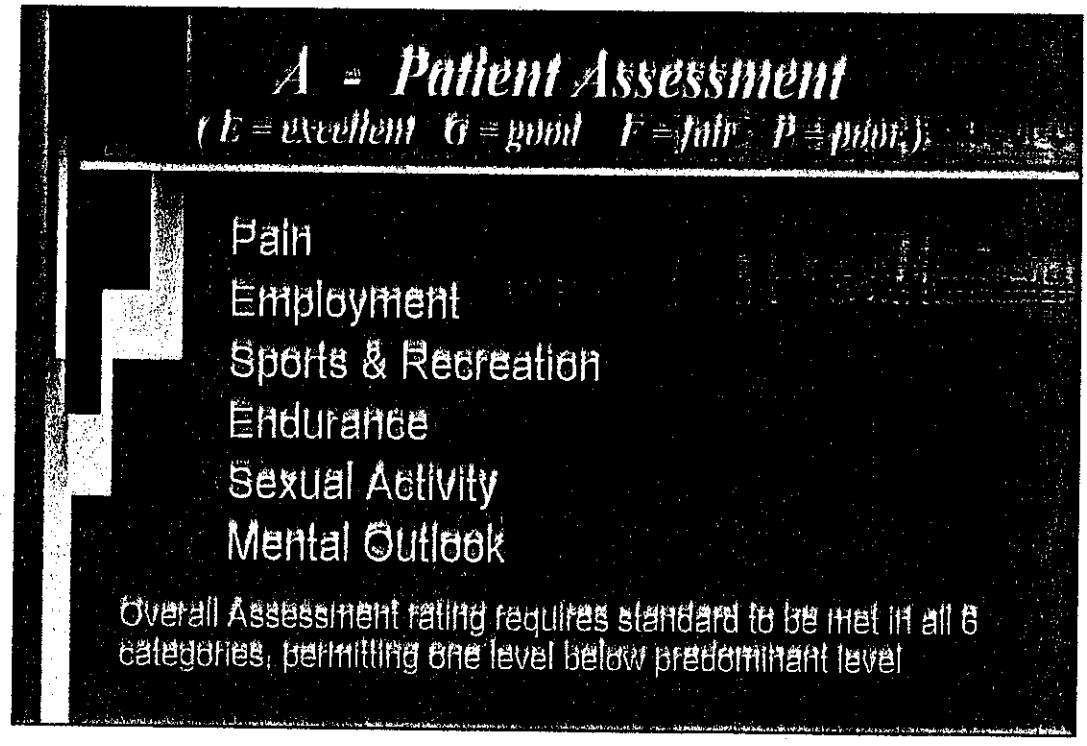


Similarly, the new back level procedures were predominantly decompressions.

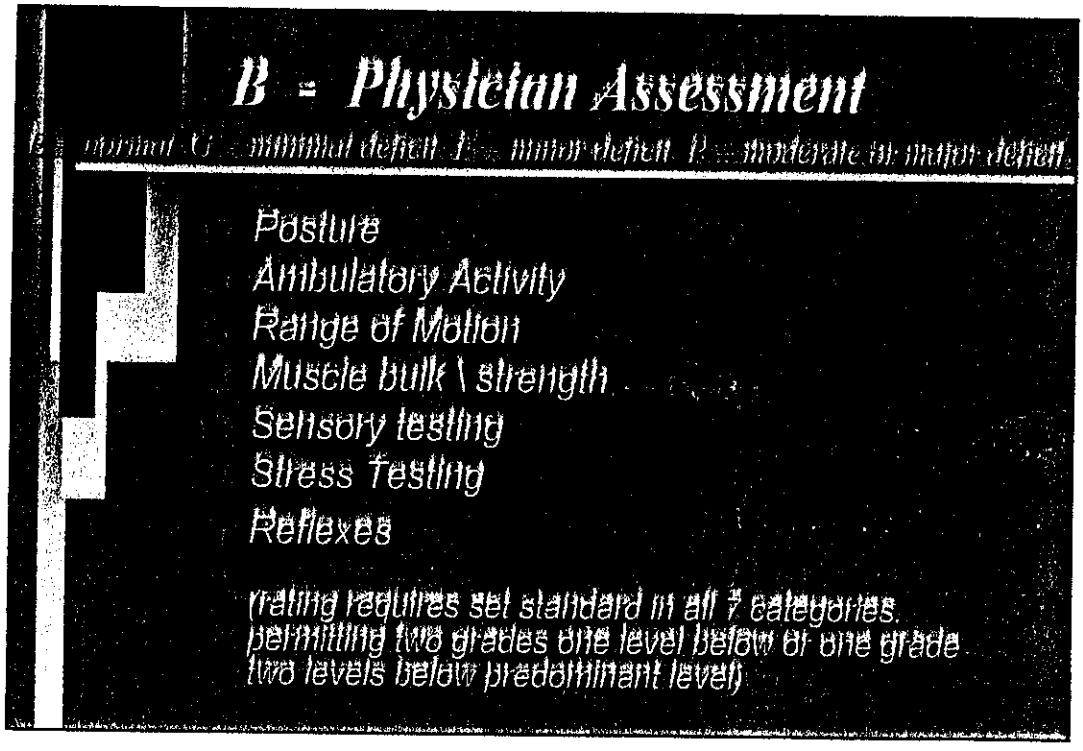


I developed several measures to assess clinical outcomes, similar in many respects to one described by Greenough & Fraser (Spine : 17 pp 36-42)

These included the following …



The patient's own assessment of outcome was graded as Excellent, Good, Fair or Poor, based on 6 key factors. The overall Patient Assessment rating basically required that rating for all 6 factors but would allow for one grade below the predominant grade..



Physician assessment was also carried out using a similar method of grading on 7 key factors but permitted two grades below the predominant grade or one grade two grades below the predominant grade.

Where patient and physician assessments did not correspond, the patient's assessment prevailed.

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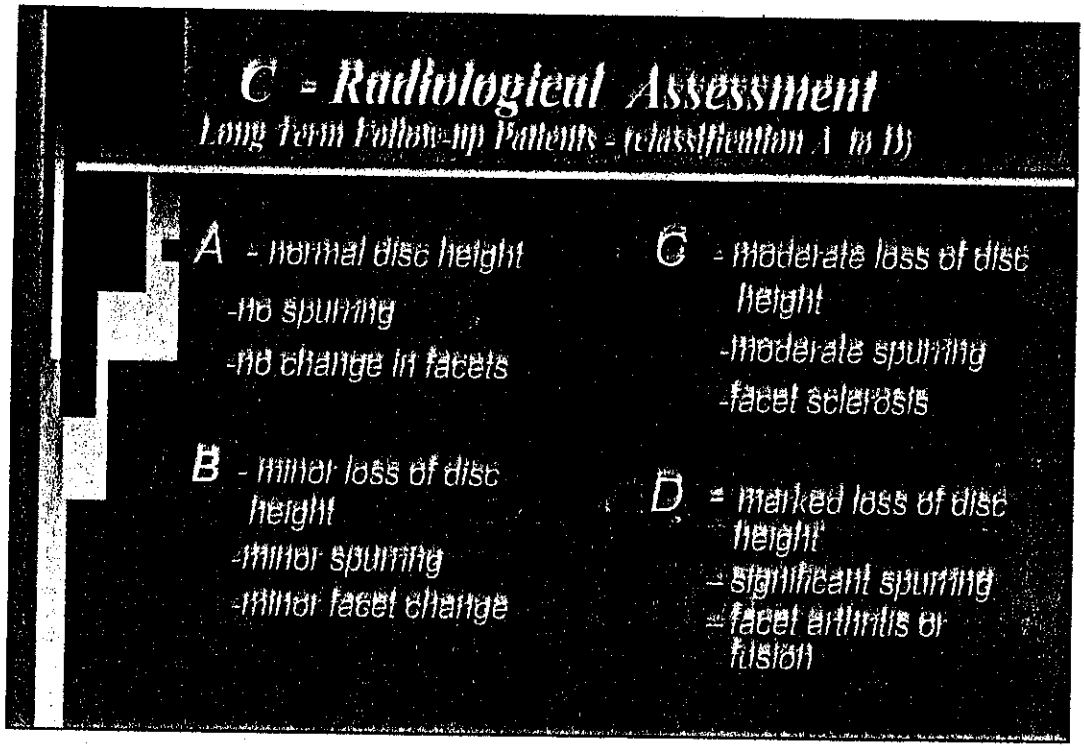

A radiological grading of A to D was judged by the loss of disc height and secondary vertebral changes.

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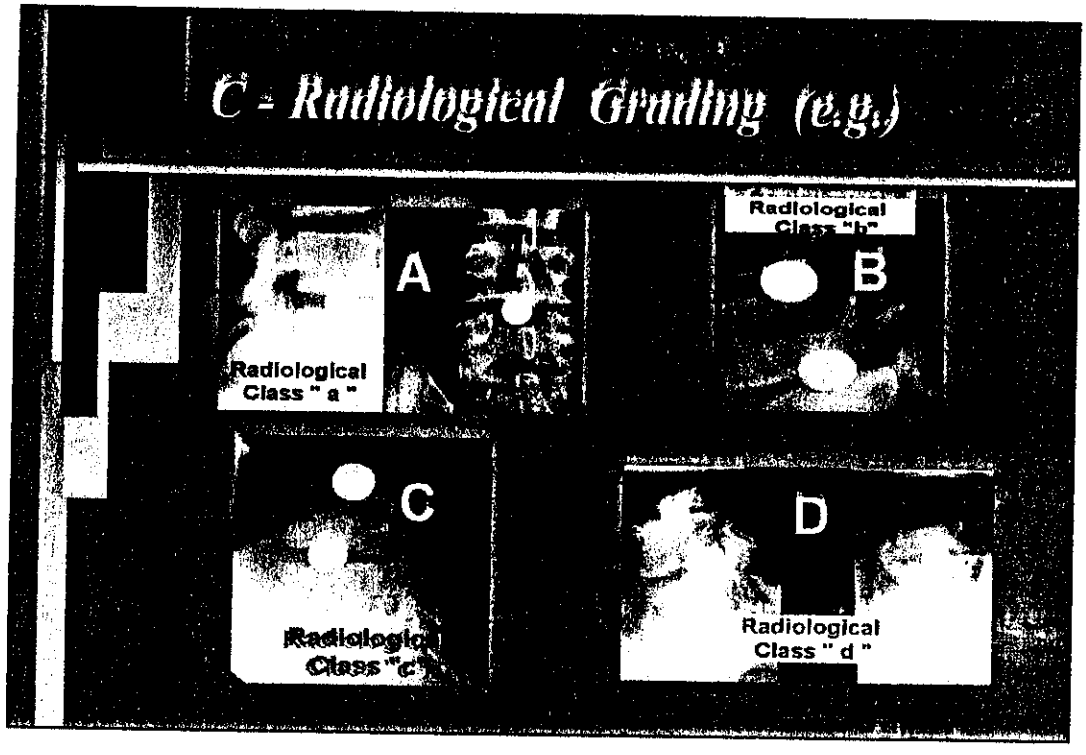

Here are some X-rays showing examples of A to D gradings. Again, A represents normal disc height, down to D which represents marked loss of disc height with significant spurring, facet arthritis, and/or fusion.

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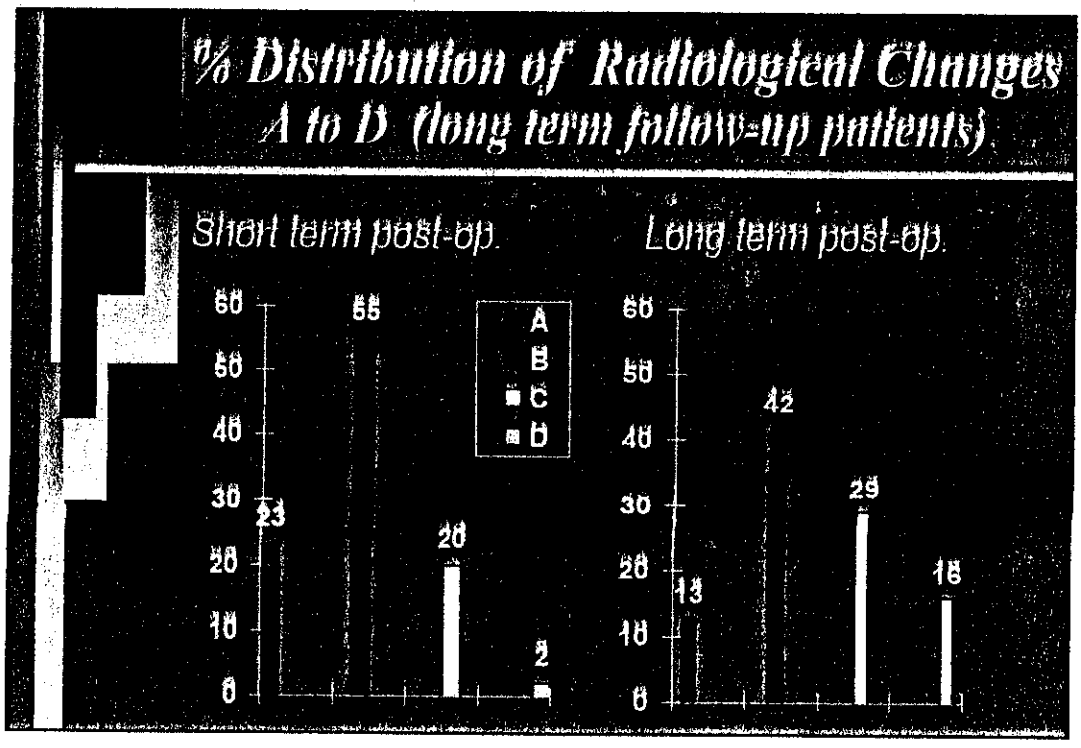

Radiological grades were determined at 3 to 5 years after surgery and 10-20 years after surgery.

As the graphs show, most patients showed some disc collapse over time.

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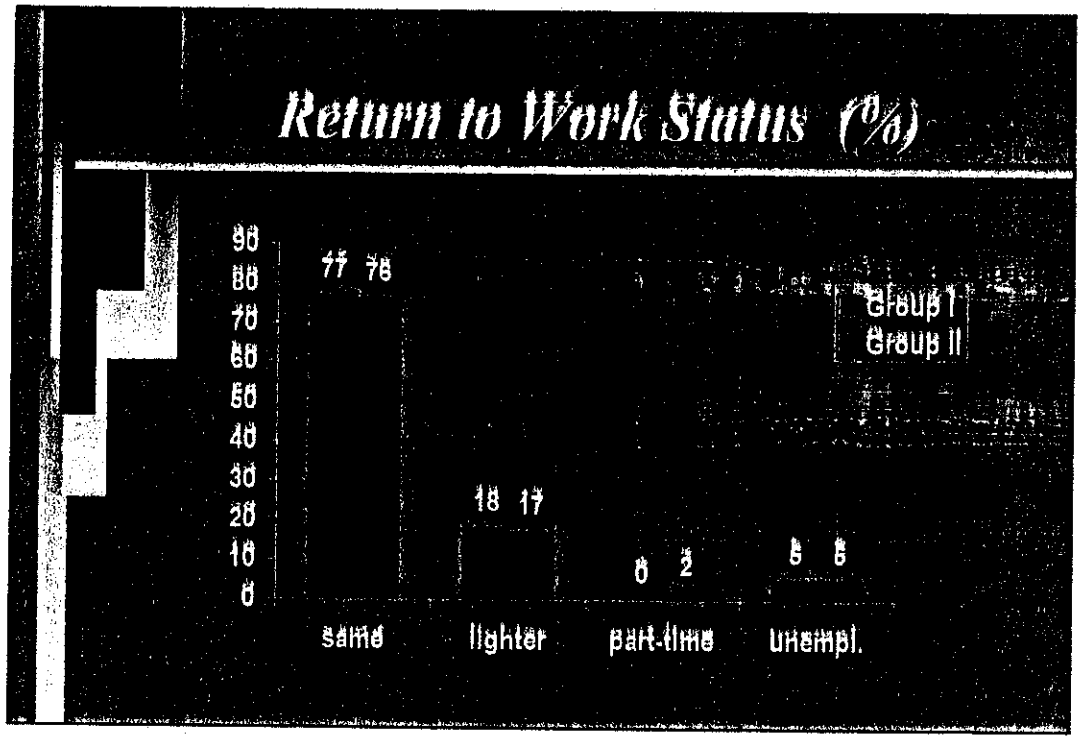

One of the most significant results was that approximately 95% of all patients returned to work, 80% of those to their regular jobs.

More than 90% had been disabled from work at the time of surgery.

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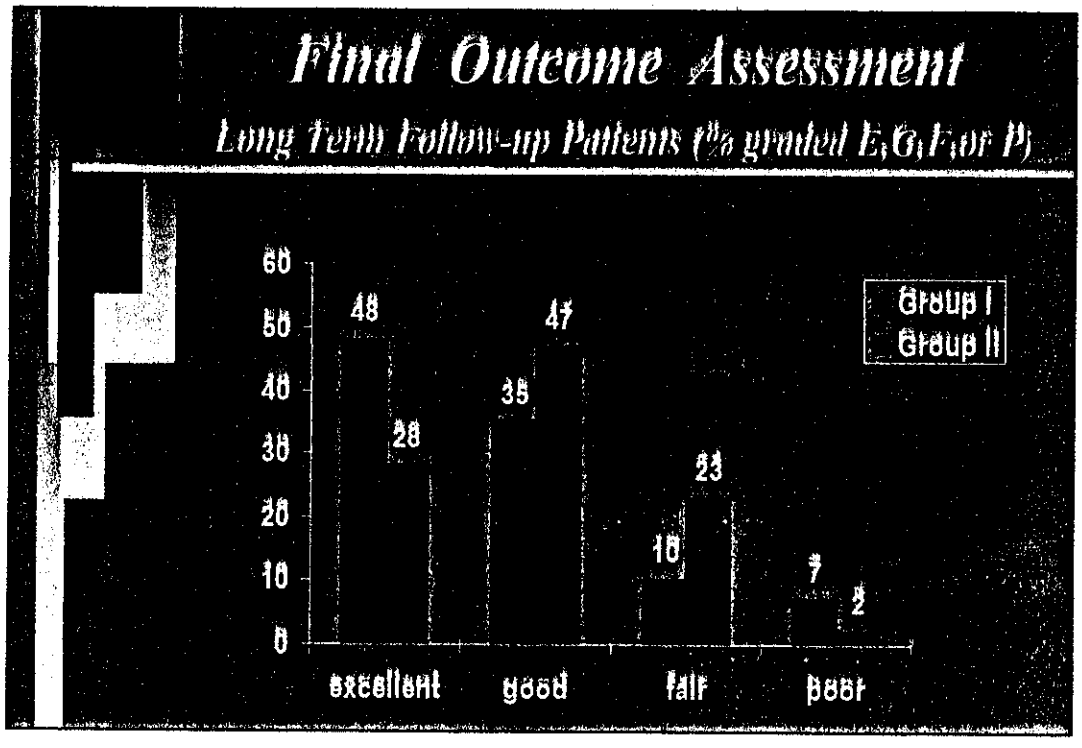
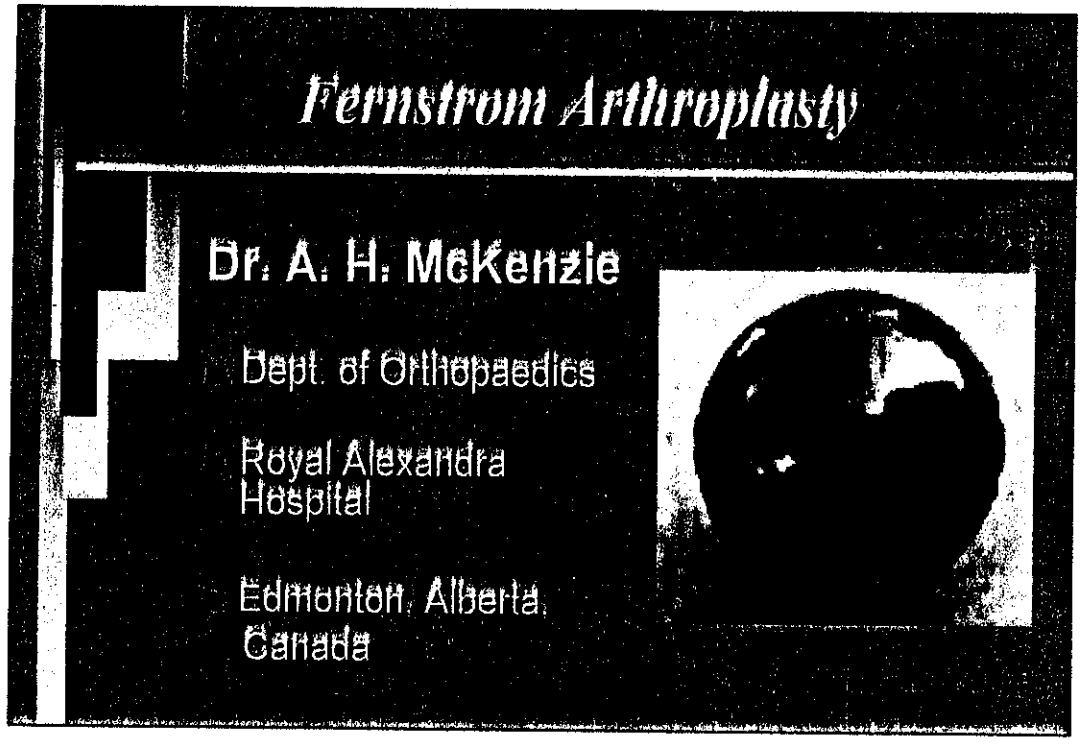


A final or overall outcome assessment combined the patient, physician, and radiological assessments and the patient's return-to-work results.

Final outcome assessment indicated that the best results occurred in Group I patients, but that generally good results occurred in Group II patients as well.



Thank you for your attention.

Go have a ball!

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AFFIDAVIT

Of Alvin H. McKenzie, M.D.

Alvin H. McKenzie, M.D. hereby deposes and attests to the following statements of fact:

1. I reside in Edmonton, Alberta, Canada and am a practicing orthopaedic surgeon.
2. This affidavit is to clarify my experience with the use of solid spinal spheres as a stabilizing and arthroplasty device in the human spine prior to May 28, 1976, and primarily between October, 1969 and late 1972. The Spinal Sphere System developed by Stille and DePuy in consultation with Dr. Ulf Fernstrom was based on the solid spinal sphere system developed by Austenal in consultation with Dr. Paul Harmon in 1957, to restore stability to intervertebral disc levels, to stand alone as an arthroplasty or to provide segmental intervertebral stabilization as an aid to interbody fusion for degenerative disc disease, facet arthritis, degenerative listhesis and pseudarthrosis.
3. I utilized the Spinal Sphere System developed and supplied by Stille and DePuy in consultation with Dr. Ulf Fernstrom for segmental arthroplasty of the cervical and lumbar spine (C2 to S1 intervertebral disc spaces) to provide spinal stabilization and motion preservation at one or more levels. The spheres were inserted from a posterior approach in the lumbar spine and an anterior approach in the cervical spine, and placed in the middle of the disc space and slightly posteriorly, usually in the nuclear recesses between the vertebral bodies. This placement mimicked the kinematic center of the functional spinal unit (at each level or at multiple levels).

4. I promoted the device for the following medical indications:

   to maintain disc height, mobility and stability after discectomy for disc protrusion; and to restore stability and improve facet alignment and functional motion after discectomy for painful degenerative spondylosis with instability and/or early to moderate facet arthritis. Other conditions were implied since no restrictions in use were given; in other words Howmedica (Austenal) and Stille and DePuy did not restrict the indicated use of the Spinal Sphere at any time.

5. I personally used the Spinal Sphere System primarily in the lumbar spine from a posterior approach and in the cervical spine from an anterior approach. However none of the companies or myself ever restricted the use to any segment of the spine, provided that the Sphere could be safely fitted within the circumferential confines of the host intervertebral space. Such use was implied in the term 'spinal' that was used to describe both the Harmon spheres and the Fernstrom arthroplasty spheres that were intended to be used anywhere in the spine.

6. The surgical technique of use for each indication did not vary according to the level of lumbar implantation or medical condition being treated. The routine surgical technique consisted of first exposing the lumbar spine from a posterior direction at the level(s) to be implanted. The soft tissue attached to the level(s) of implantation would be released and retracted. A laminotomy would be developed at the point of posterior entry sufficient to allow entry of the prosthetic sphere. A discectomy would be performed, followed by complete excision of the degenerative nucleus pulposus and preparation of the nuclear recess. Spinal Sphere sizers were used to determine the appropriate diameter of implant to restore stability to the disc level. Finally, the

appropriate sized sphere would be placed in the nuclear recess of the disc space utilizing an attached inserter or a punch. This process would be repeated if multiple levels were indicated.

7. I, and other surgeons, used the spheres prior to May 28, 1976. I also promoted the use of the device prior to May 28,1976, acknowledging that the instrument developers and suppliers were Stille and DePuy. Dr. Paul Harmon (of West Covina, CA) promoted the Harmon Spinal Sphere for use in the disc space for degenerative disc disease as developed by Austenal prior to May 28, 1976.
8. Most of the medical records and x-rays of my patients who had the Spinal Spheres implanted between 1969 and 1988 are still available (approximately 100 total). I have provided copies of my records, which are true, accurate and complete.
9. Through correspondence with Dr. Paul Harmon in 1969, I know Austenal manufactured Vitallium spheres for Dr. Harmon's use from 1959 to 1961. These spheres were not part of any research project, and were commercially available. Dr. Harmon forwarded to me his remaining inventory of spheres which remain in my possession today. Each sphere is packaged and referenced by an Austenal catalog number for the Harmon Spinal Spheres.
10. In addition to the spheres sent to me by Dr. Harmon in 1969, I was in contact with the Stille Company of Stockholm, Sweden and the DePuy Manufacturing Company of Warsaw, Indiana. Stille and DePuy supplied me with implants and instruments for the sphere procedure.
11. I promoted the use of the sphere procedure to U.S. surgeons at the 1971 Canadian Orthopaedic Association Meeting. As noted in the enclosed course brochure,

twenty U.S. surgeons were in attendance at the meeting. The program provides reference to the date and time of my presentation.

12. A copy of the relevant page from my CV is attached to this affidavit confirming the title, place, and year of other sphere presentations. The surgical procedure slides from a 1997 talk were taken in whole or in part from the 1972 presentation to the Canadian Orthopaedic Association Meeting. Therefore, although the presentation itself was not retained, graphic illustrations demonstrating the procedure are available. This evidence proves that as early as 1972 I was promoting the Spinal Sphere System for arthroplasty as then instrumented by Stille and DePuy.

13. All of the information that I have been able to find on the meetings in which I participated prior to 1976 is attached to this affidavit.

14. I have other sources of publications, presentations, and literature etc. that describe and promote the use of the Spinal Sphere System for spinal arthroplasty and for its indication in post-operative discectomy, degenerative disc disease and segmental instability.

15. In addition to using the spheres as part of my orthopaedic practice, I was also the recipient of intervertebral spheres at both the L4-L5 and L5-S1 levels of my spine in surgery conducted by Dr. Ulf Fernström, of Sweden, in May of 1972. He performed a 2-level procedure on my own lumbar spine for painful disc ruptures with radiculopathy at both levels. Since then, I have had no complications from the procedures, have not needed any subsequent spinal surgeries and have maintained the mobility of my spine. Overall, my outcome has allowed me to enjoy a robust pain-free lifestyle.

16. I have no financial interests in Stille, DePuy, Howmedica (Austenal), and/or Medtronic Sofamor Danek or any of their related companies. I have not received and will not receive anything of value as compensation for this affidavit.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Alvin H. McKenzie, M.D. DATE: Apr. 8, 2004.

PROVINCE OF ALBERTA

CITY OF EDMONTON

Sworn to and Subscribed before me this 8 day of APRIL, 2004

My Commission Expires: _____

Notary Public (b) (6) NANCY J. McKENZIE BARRISTER & SOLICITOR

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CONFIDENTIAL

Medtronic
SOFAMOR DANEK

Design Verification Test Report

TR07-103

(b) (4)

ASTM F2077 Fatigue and Static Compression Testing of the 11 mm Diameter PEEK Satellite Stabilization Sphere

Testing Performed by (b) (4)

(b) (4)

Prepared By:

Reviewed By:

Approved By:

(b) (4)

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SATELLITE® Spinal System Implants

Implant Description	Reference Number	Levels of Attachment[1]	510(k) NUMBER
PEEK Implants			
SATELLITE® Spinal Implant 11mm diameter	**9000211**	**L/S**	**New**
SATELLITE® Spinal Implant 12mm diameter	**9000212**	**L/S**	**New**
SATELLITE® Spinal Implant 13mm diameter	**9000213**	**L/S**	**New**
SATELLITE® Spinal Implant 14mm diameter	**9000214**	**L/S**	**New**
SATELLITE® Spinal Implant 15mm diameter	**9000215**	**L/S**	**New**
SATELLITE® Spinal Implant 16mm diameter	**9000216**	**L/S**	**New**
Cobalt Chrome Implants			
SATELLITE® Spinal Implant 9.5mm diameter	8000209	L/S	K051320
SATELLITE® Spinal Implant 10mm diameter	8000210	L/S	K051320
SATELLITE® Spinal Implant 11mm diameter	8000211	L/S	K051320
SATELLITE® Spinal Implant 12mm diameter	8000212	L/S	K051320
SATELLITE® Spinal Implant 13mm diameter	8000213	L/S	K051320
SATELLITE® Spinal Implant 14mm diameter	8000214	L/S	K051320
SATELLITE® Spinal Implant 15mm diameter	8000215	L/S	K051320
SATELLITE® Spinal Implant 16mm diameter	8000216	L/S	K051320
SATELLITE® Spinal Implant 17mm diameter	8000217	L/S	K051320
SATELLITE® Spinal Implant 18mm diameter	8000218	L/S	K051320
SATELLITE® Spinal Implant 19mm diameter	8000219	L/S	K051320

For marketing or other reasons Medtronic Sofamor Danek reserves the right to change the tradename of any or all of the listed components. For example, the company may decide to make the SATELLITE® Spinal System its flagship system and discontinue or lose any individual system identity yet keep the components identified in this table as part of the SATELLITE® Spinal System. If that occurs, the affected components would begin receiving the SATELLITE® Spinal System package insert and the SATELLITE® trade name in replacement of its existing system name and insert. All other company labeling would be appropriately modified."

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[1] L= Lumbar, S = Sacrum

(b) (4)

Eur Spine J (2006) 15: 149–156
DOI 10.1007/s00586-005-0915-5

ORIGINAL ARTICLE

Stephen J. Ferguson
Judith M. A. Visser
Anne Polikeit

The long-term mechanical integrity of non-reinforced PEEK-OPTIMA polymer for demanding spinal applications: experimental and finite-element analysis

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Abstract Polyetheretherketone (PEEK) is a novel polymer with potential advantages for its use in demanding orthopaedic applications (e.g. intervertebral cages). However, the influence of a physiological environment on the mechanical stability of PEEK has not been reported. Furthermore, the suitability of the polymer for use in highly stressed spinal implants such as intervertebral cages has not been investigated. Therefore, a combined experimental and analytical study was performed to address these open questions. A quasi-static mechanical compression test was performed to compare the initial mechanical properties of PEEK-OPTIMA polymer in a dry, room-temperature and in an aqueous, 37°C environment ($n = 10$ per group). The creep behaviour of cylindrical PEEK polymer specimens ($n = 6$) was measured in a simulated physiological environment at an applied stress level of 10 MPa for a loading duration of 2000 hours (12 weeks). To compare the biomechanical performance of different intervertebral cage types made from PEEK and titanium under complex loading conditions, a three-dimensional finite element model of a functional spinal unit was created. The elastic modulus of PEEK polymer specimens in a physiological environment was 1.8% lower than that of specimens tested at dry, room temperature conditions ($P < 0.001$). The results from the creep test showed an average creep strain of less than 0.1% after 2000 hours of loading. The finite element analysis demonstrated high strain and stress concentrations at the bone/implant interface, emphasizing the importance of cage geometry for load distribution. The stress and strain maxima in the implants were well below the material strength limits of PEEK. In summary, the experimental results verified the mechanical stability of the PEEK-OPTIMA polymer in a simulated physiological environment, and over extended loading periods. Finite element analysis supported the use of PEEK-OPTIMA for load-bearing intervertebral implants.

Keywords PEEK · Material properties · Creep · Cages · Fusion

Introduction

Polyetheretherketone (PEEK) polymer has been proposed for use in demanding, long-term orthopaedic applications. PEEK is a high-performance biomaterial which combines chemical and hydrolysis resistance, resistance to the effects of ionizing radiation, high strength and good tribological properties with extensive biocompatibility [19, 27, 37]. PEEK is a thermoplastic which can be easily processed into complex implant

forms. Moreover, this biomaterial can be repeatedly sterilized using conventional steam, gamma and ethylene oxide processes without significant deterioration.

Implants based on the PEEK polymer have been developed in the last decade as an alternative to conventional metallic devices. PEEK devices may provide several advantages over the use of conventional orthopaedic materials, including the lack of metal allergies, radiolucency, low artefact on magnetic resonance imaging scans and the possibility to tailor mechanical properties [7]. PEEK polymer devices were first reported for fracture fixation, using carbon reinforcement in a PEEK matrix [8, 17]. Iso-elastic, carbon-reinforced PEEK hip prosthesis components have been proposed to address the modulus mismatch between the bone and implant material in order to improve load transfer [2, 3, 18, 34]. Uncoated and titanium-coated PEEK has been suggested for use in dental implantology [9, 11].

The in vivo performance of orthopaedic devices is highly dependent on the intrinsic mechanical properties of the chosen implant material. Bulk mechanical, interfacial and wear properties for hydroxyapatite- and carbon-reinforced PEEK polymers have been reported [1, 4, 8, 23, 25, 39]. However, non-reinforced PEEK is increasingly the material of choice for orthopaedic applications. No data for the initial mechanical properties of pure PEEK polymer in a physiological environment have been published. An aqueous, body temperature environment has been shown to substantially influence the mechanical properties of other medical-grade polymers such as ultra-high molecular weight polyethylene (UHMWPE) [12, 21]. Furthermore, orthopaedic polymers are susceptible to creep, the time dependent, non-recoverable material flow in response to continuous loading, which can result in a significant alteration of implant geometry and biomechanical performance. Creep deformation of pure PEEK in a dry environment has been reported to vary from less than 0.1% per month at room temperature to more than 1% per month at elevated temperatures for stress levels relevant to orthopaedic applications (5–10 MPa) [36].

An increasing number of PEEK devices for interbody fusion are now available. A primary advantage of fusion devices made from PEEK is the undisturbed radiographic evaluation of progression towards bone fusion. The lower elastic modulus of PEEK may minimize stress shielding effects, or even potentially have a stimulatory effect on bone generation [16, 27] and lead to a better fusion than that achieved with metallic cages. Furthermore, PEEK has been shown to be harmless to the spinal cord in site-specific biocompatibility tests [32]. Intervertebral cages are subjected in vivo to complex, three-dimensional loading conditions characterized by high compressive loads which vary spatially and temporally with flexion, extension and side-bending motions. Biomechanical testing and pre-clinical results have recently been reported for PEEK cervical cages and/or anterior plating devices for spinal fusion [10, 13, 20, 20, 24, 33, 38]. While the biomechanical performance of conventional metallic lumbar intervertebral devices has been extensively evaluated through in vitro testing [28] and finite element analysis [30, 31], the performance of PEEK lumbar fusion cages has not been reported.

Polyetheretherketone polymer is a promising material for use in demanding spinal applications. However, the mechanical integrity of the polymer in a physiological environment and its suitability for use in highly stressed implants such as intervertebral cages have not been adequately investigated. Therefore, a combined experimental and analytical study was performed to address these open questions with the following specific goals: (1) to compare the initial mechanical properties of PEEK-OPTIMA in dry, room temperature and in aqueous, body temperature conditions, (2) to determine the creep properties of this material in an aqueous, body-temperature environment and (3) to compare the biomechanical performance of different intervertebral cage types made from the PEEK polymer to that of titanium cages under complex loading conditions.

Methods

Quasi-static compressive testing

A compressive test was designed according to the American Society for Testing and Materials (ASTM) testing standard D695-02 [6] to determine the elastic modulus. Cylindrical test specimens were machined from stock PEEK-OPTIMA[1] LT1 rod material (Grade LTIR30, Invibio, Lancashire, UK), with dimensions 12.7 mm diameter by 50.8 mm length to fulfil the required slenderness ratio of 11–16. Two groups ($n = 10$ per group) were tested. Specimens to be tested in a simulated physiological environment were conditioned in a saline solution (0.15 M NaCl) at 37°C (±1°C) for 48 h before testing. The compressive tests were performed on an MTS 858 Bionix servohydraulic testing machine (MTS Systems Corporation, Eden Prairie, MN, USA). Specimens were compressed at 0.02 mm/s to a maximum load of 5,000 N. The samples were centred under the hydraulic actuator and compressive loads were applied through a ball joint to ensure a purely axial force. The compressive force data were measured by an integrated load cell (±1 N), displacement data were measured by the position of the hydraulic actuator (±1 μm) and collected at a sampling rate of 10 Hz. From force, length and geometric data, the engineering stress and strain were calculated. The modulus of elas-

[1] PEEK-OPTIMA is a specific medical grade of PEEK, supplied for use in human implantable devices.

ticity was determined by taking the tangent to the linear portion of the stress–strain curve. Differences in elastic modulus between groups were evaluated for statistical significance using a Student's *t*-test, with a significance level of $P = 0.05$.

Creep testing

The creep test was based on ASTM D2990-01 [5], with some practical modifications. Cylindrical specimens were machined with a diameter of 6 mm and a length of 22.5 mm to fulfil the required slenderness ratio. A multi-station creep testing apparatus was constructed to load three specimens simultaneously and independently. The testing apparatus was designed to apply a constant vertical load on each of the specimens separately via a second class lever arrangement using weights suspended from a freely-pivoting cantilevered beam (Fig. 1). The load was transferred from the beam to the samples by a ball joint to ensure pure axial compressive loading. Specimens were contained within a saline bath (0.15 M NaCl + 0.01% sodium azide to prevent bacterial growth), heated to 37°C (± 1°C) by an immersion heater. The samples were conditioned in the bath for 70 h prior to loading. The testing apparatus was placed in a stable environment, free from vibrations. An axial compressive stress of 10 MPa was chosen for the nominal load, based on preliminary finite element analyses of the stress state within representative PEEK intervertebral cage designs during daily activities (unpublished data). Six specimens were loaded and four control samples were kept unloaded for reference in the same bath conditions.

The length of each sample was measured prior to loading with a precision micrometer (Mitutoyo, Japan; ± 1 μm). The lengths of the samples, loaded and reference, were measured at 6, 12 and 30 min ; 1, 2, 5, 20, 70, 100, 200, 500, 700, 1,000 and 2000 h (12 weeks) after loading was begun. At each of these time points, the samples were briefly unloaded and elastic strain recovery allowed. Each sample was taken out of the bath, blotted quickly and the length measured immediately with the precision micrometer. After each measurement, the loaded samples were replaced in the loading set-up and the reference samples in their reference position. The total time duration of the measurement procedure was approximately 5 min. Although measuring the creep of unloaded specimens is in contrast to the ASTM specification, this procedure has been employed previously for the determination of creep in UHMWPE specimens and eliminates errors in specimen length originating from play in the linkages of the apparatus [22].

Compressive creep was calculated for each specimen by subtracting the specimen length measured at each time interval from the initial length of the specimen. Compressive creep strain was calculated by dividing the compressive creep by the original length of the specimen. Each creep strain measurement was then corrected by subtracting the average strain of the reference samples, measured at the same time and temperature.

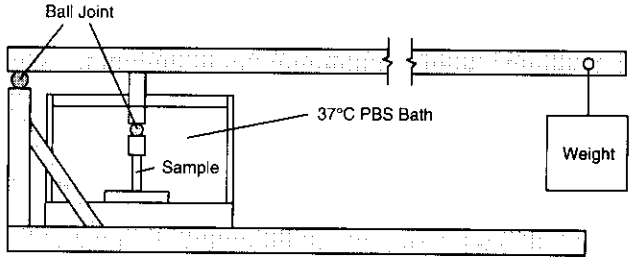

Fig. 1 Schematic illustration of creep-testing apparatus

Finite element model

An accurate three-dimensional finite element (FE) model of the convex SynCage-LR (Synthes, Bettlach, CH, USA) was developed and inserted in a validated, three-dimensional, nonlinear FE model of a L2–L3 functional spinal unit (FSU) (Fig. 2). Details of the model development have been given elsewhere [30, 31], and are briefly summarised here. The geometry of the model was based on CT scans of a healthy, young cadaver specimen. The material properties were adapted from previous finite element studies and assumed to be linear, homogeneous and isotropic. For validation, the results of this model were compared to experimental data [14, 29]. The relationship between force and displacement, the resulting nucleus pressure as well as the maximum principal strain at several locations on the vertebra were found to be in good agreement.

An anterior insertion of an intervertebral cage was modelled by removing the anterior longitudinal ligament, the nucleus pulposus and the necessary amount of fibre and annular elements. The cage size was chosen

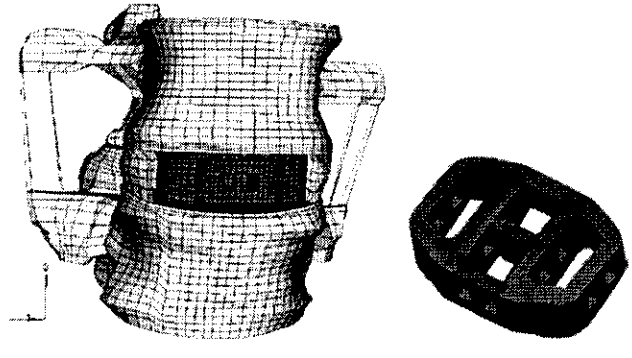

Fig. 2 Finite element model of a L2–L3 functional spinal unit (*left*) and the SynCage-LR intervertebral cage (*right*)

according to the space between the vertebrae, as proposed by the manufacturer, to restore lordosis and disc height.

Changes in the load transfer due to the implantation were investigated comparing intact and instrumented FSUs. Instrumented FSUs included either a modified SynCage (flattened inferior and superior faces) or a convex SynCage-LR made from either PEEK or titanium to assess design and material differences. A nonlinear, three-dimensional contact definition was used between the implant and the neighbouring endplates for the SynCage-LR. Between the surfaces of the simplified, flat SynCage and the anatomically curved endplates, this contact definition was not appropriate. Therefore gap elements were introduced here, with the contact direction chosen perpendicular to the cage surfaces. To include the effect of the small teeth on the original cage surfaces, a friction coefficient of 0.8 was defined for all contact interactions. The model was loaded with either pure axial compression (1,000 N) or pure bending moments (up to 8 Nm, with a 400 N axial compressive preload) in all three anatomical planes. ABAQUS 6.3 was used to solve all models (HKS, Pawtucket, USA).

Results

Material property testing

The modulus of elasticity of PEEK-OPTIMA samples tested in a 37°C aqueous environment was 1.8% lower than that of samples tested in a dry, room temperature environment. The standard deviation of the calculated modulus values was very low. Therefore, while temperature and humidity had a statistically significant ($P < 0.001$) influence on the elastic modulus, the difference was nevertheless small (Table 1).

The corrected creep strains were plotted as a function of linear and logarithmic time (Fig. 3). The strain increased more rapidly in the first few hours, followed by a reduced rate of creep later in the experiment, approaching a steady state after 2000 hours of loading. Approximately 80% of the total creep strain was achieved within the first 200 h. Creep strain data was best fit by a logarithmic function ($r^2 = 0.964$) with an average slope of 5.715×10^{-5} (1/log[min]) for an applied pressure of 10 MPa. The total creep after 2000 hours at a stress level of 10 MPa was less than 0.1%. For comparison, the total corrected creep strain for PEEK polymer tested in a dry, room-temperature environment is approximately 0.04% [36].

Table 1 Initial elastic modulus

	Elastic modulus (GPa) @ Dry, room temperature	Elastic Modulus (GPa) @ Wet, 37°C
Average	3.51	3.57
Standard deviation	0.02	0.02

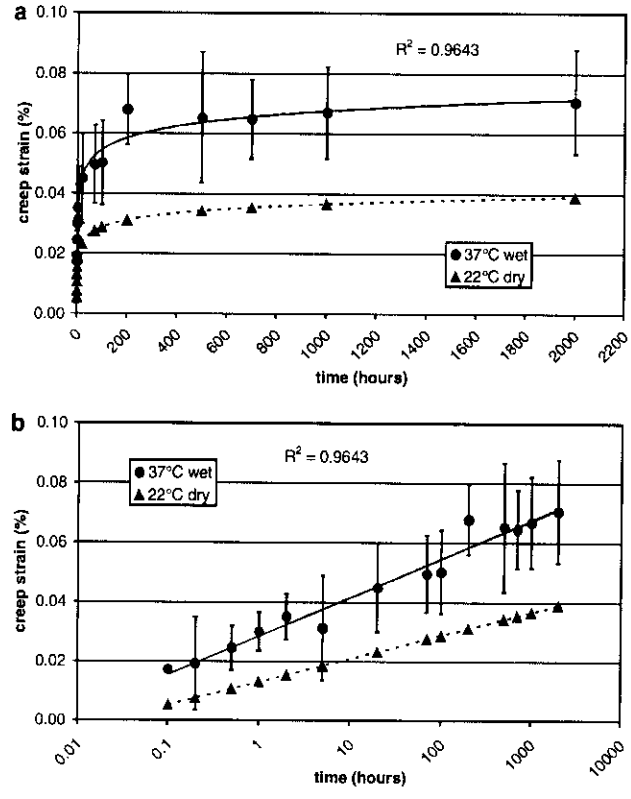

Fig. 3 Average corrected creep strain for PEEK-OPTIMA as a function of **a** linear and **b** logarithmic time. The total creep strain after 2000 hours in a 37°C aqueous environment at an applied stress of 10 MPa was on average less than 0.1%. For reference, the corrected creep strain for standard PEEK polymer (450 G) in a dry, 23°C environment is also plotted [34]

Finite element analysis

The insertion of an intervertebral cage substantially altered the load transfer through the functional spinal unit for pure compression (Fig. 4), flexion-extension (Fig. 5), lateral bending (Fig. 6) and axial rotation. Stress and strain maxima were increased for all cage types compared to the intact situation. For example, for compression loading, L2 inferior endplate maximum strain values increased by 928% and 923%, respectively, following insertion of titanium and PEEK cages of similar geometry. For flexion loading, maximum strain values within the cancellous bone of L3 increased by 719% and 741%, respectively, following insertion of PEEK and titanium cages. Similar trends were observed for all loading conditions. Differences in the altered stress and

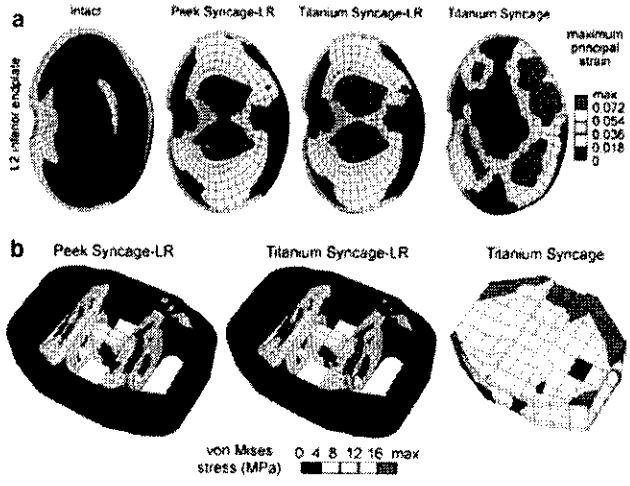

Fig. 4 **a** Maximal principal strain distribution in the inferior L2 endplate due to 1,000 N of compression. *From left to right* Intact, PEEK SynCage-LR, titanium SynCage-LR, flat SynCage. **b** Von Mises stress distribution in the cages due to 1,000 N of compression. *From left to right* PEEK SynCage-LR, titanium SynCage-LR, flat SynCage

strain distributions were more evident between the two cage designs (flat SynCage vs. convex SynCage-LR) than for the two materials investigated (PEEK and titanium), Fig. 4a. Maximum contact stresses with the flat SynCage tended to be locally distributed around the periphery of the implant, whereas the contact stresses with the SynCage-LR were more evenly distributed across the centre of the endplate.

Regarding the material differences, titanium cages produced increased areas of high strain within the adjacent vertebrae under compression and lateral bending. Additionally the resulting strain maxima were different: for 8 Nm of flexion, for example, the strain maximum in the cancellous bone of L3 was 22% higher, following the insertion of a titanium cage than after the implantation of one made from PEEK. In the cages themselves, slightly lower stresses and decreased areas of high stresses were seen in a SynCage-LR made from PEEK, compared to an identical design in titanium, for compression, flexion, lateral bending and axial rotation, Figs. 4b, 5b, 6b. Maximum von Mises stresses within the PEEK cage were 45.7 MPa, 31.5 MPa, 52.6 MPa and 32.7 MPa for 1,000 N compression, 8 Nm flexion, 8 Nm lateral bending and 2.5 Nm axial rotation respectively.

Numerical singularities precluded solution of the intact model for extension moments greater than 5 Nm and axial rotation greater than 2.5 Nm for the models including a cage.

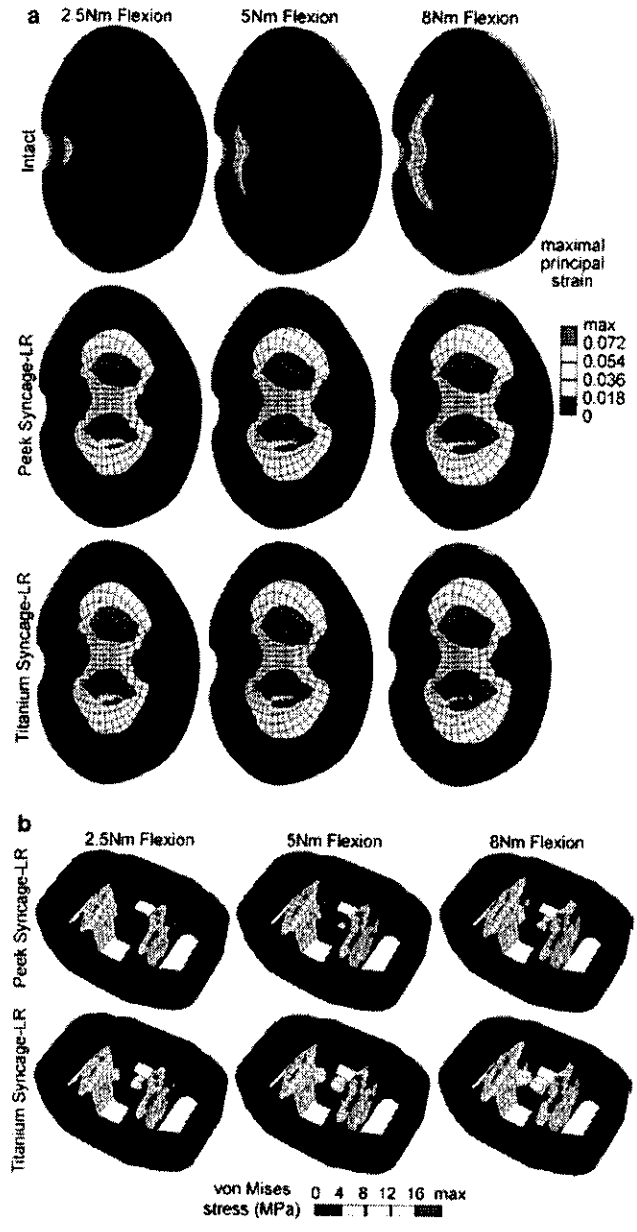

Fig. 5 **a** Maximal principal strain in the inferior endplate of L2 due to flexion. *From left to right* 2.5 Nm, 5 Nm, 8 Nm. *From top to bottom* Intact, PEEK SynCage-LR, titanium SynCage-LR. **b** Von Mises stress in the SynCage-LR due to flexion. *From left to right* 2.5 Nm, 5 Nm, 8 Nm. *Top row* PEEK SynCage-LR, *bottom row* Titanium SynCage-LR

Discussion

Although PEEK has been proposed for use in demanding orthopaedic applications, the mechanical integrity of the polymer in a physiological environment has not been documented. Furthermore, the suitability of the polymer for use in highly stressed implants such as intervertebral cages and the potential biomechanical advantages of PEEK implants for spinal applications have not been investigated. Therefore, a combined experimental and analytical study was performed to address these open questions.

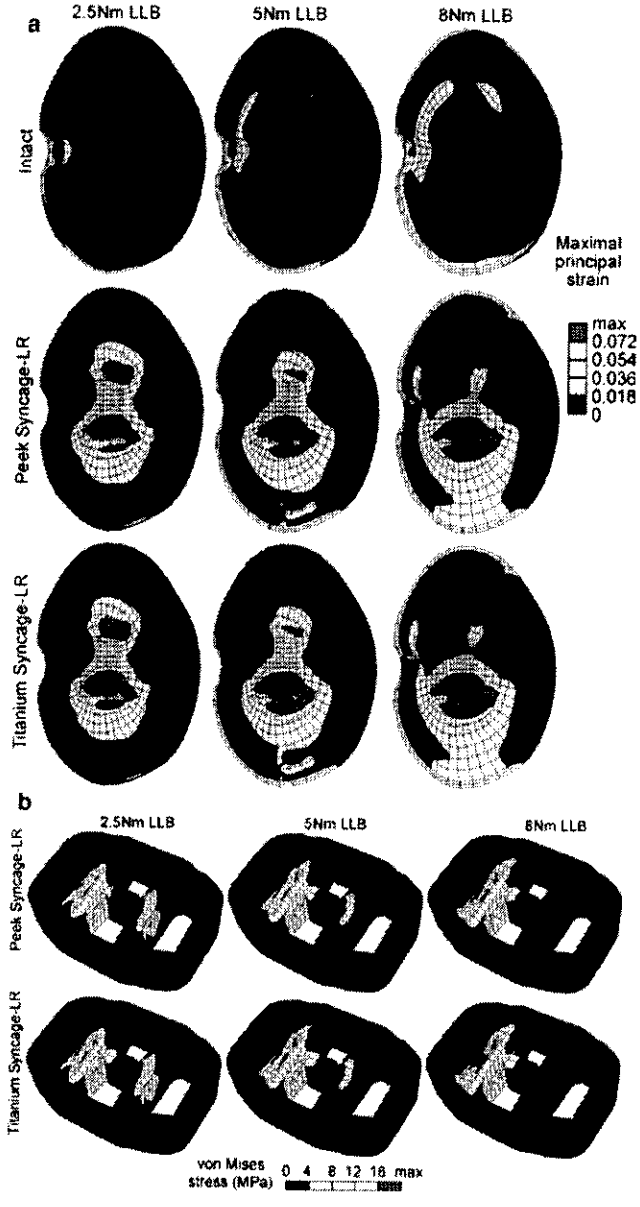

Fig. 6 **a** Maximal principal strain in the inferior endplate of L2 due to left lateral bending. *From left to right* 2.5 Nm, 5 Nm, 8 Nm. *From top to bottom* Intact, PEEK SynCage-LR, titanium SynCage-LR. **b** Von Mises stress in the SynCage-LR due to left lateral bending. *From left to right* 2.5 Nm, 5 Nm, 8 Nm. *Top row* PEEK SynCage-LR, *bottom row* Titanium SynCage-LR

Testing in an aqueous 37°C environment showed a statistically significant but marginal influence on the initial mechanical properties of PEEK-OPTIMA. The measured difference in properties would not invalidate implant designs based on previously published material properties obtained in a dry, room temperature testing. PEEK-OPTIMA can therefore be considered mechanically stable in vivo, as it does not demonstrate the substantial changes in mechanical properties with temperature and hydration which have been observed for other medical grade polymers such as polyurethanes and polyethylenes [12, 21]. Nevertheless, final proof-testing of PEEK orthopaedic implants should be conducted in a simulated physiological environment.

The method used to measure total polymer creep did not fully conform to the ASTM testing standard. However, the chosen method eliminates inaccuracies that could be caused by play in the testing apparatus, and the same method has been used previously to determine the creep characteristics of polyethylene [22]. Furthermore, the static compressive loading represents a worst-case loading scenario for creep measurements, as no recovery of the specimens is allowed throughout the testing, in contrast to the dynamic loading experienced in vivo. The total test duration of 2000 hours far exceeds the test duration previously reported for polyethylene [22] and represents a more physiological relevant loading duration for implants designed to aid spinal fusion. The creep rate determined for PEEK-OPTIMA was approximately two orders of magnitude lower than that previously measured for medical grade polyethylene [22], whereas the total deformation of PEEK-OPTIMA was slightly increased in a 37°C, aqueous environment when compared to that measured at room temperature in a dry environment [36]. In practice, the total non-recoverable deformation of PEEK-OPTIMA would be negligible, with maximum 0.1% strain after 2000 hours at a stress level of 10 MPa, vanishingly small, compared to the time-dependent changes which could be expected in the surrounding bone due to remodelling effects. The reference samples expanded slightly during the experiment, most likely due to fluid absorption. Therefore, water absorption may counteract creep in vivo, and the corrected creep strain measured here can be considered a conservative estimate of the material's creep behaviour. These results verify the mechanical stability of the PEEK-OPTIMA polymer in a simulated physiological environment, and over extended loading periods.

The finite element analyses approximated the loading situation existing in the initial time period after the implantation. Following cage insertion, high strains and stresses were concentrated in the contact areas between the cage and endplate, underlining the importance of sufficiently large contact zones. Contact stresses below the anatomically-shaped implant with curved surfaces tended to be more broadly distributed across the central endplate, whereas contact stresses around the flat implants tended to be concentrated around the periphery of the device. However, it has been shown previously that the local endplate strength increases towards the outer edges [15], and the integrity of similar intervertebral cage designs, relying only on peripheral support, has been demonstrated in previous

experimental testing [35]. For the rather demanding loading conditions applied in the simulations, the determined maximum principal strains approached the limits of the elastic definition used for the materials in this model. Calculated local bone strains might exceed the yield strain reported for vertebral trabecular bone [26], so the possibility of local bone changes in response to mechanical loading cannot be excluded and implant subsidence may occur. However, this initial settling period might offer the possibility to achieve a larger, more congruent contact interface between cage and endplates, and in consequence, an enhanced stability. Furthermore, anterior lumbar interbody fusion with a standalone cage, as represented in this model, is a mechanically demanding application. The addition of supplemental posterior fixation (e.g. translaminar facet screws), a commonly used adjunt to the anterior implant, would provide a substantial load-sharing capacity and reduce the level of stresses generated within the vertebral bodies.

For the applied forces and moments, representing everyday loads, the stress and strain values determined in the cages themselves never approached the limits of the polymer's or titanium's intrinsic material strength. The resulting differences in load transfer due to the two cage materials were relatively small; nevertheless, a slight trend towards a more pronounced stress-shielding situation with titanium cages might be concluded from our results.

Model solutions could not be obtained for certain loading cases. The complexity of the contact definition at the cage-endplate interface, in conjunction with a realistic interface shape mismatch, resulted in a failure of the model solution at high extension and rotation moments. This numerical instability is consistent with experimental results demonstrating the limitations of standalone cages to stabilize a spinal motion segment under these types of loadings [28].

In summary, our experimental and finite element analysis established that PEEK-OPTIMA is a suitable material for load-bearing implants in the human body. Used in intervertebral cages, it performs at least as well as similar titanium implants, additionally offering the possibility of undisturbed radiographic fusion control due to its radio-translucency and potential benefits for the stimulation of bone formation due to the close match between the mechanical properties of the polymer and host bone.

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